UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE IMMUCOR, INC. SECURITIES LITIGATION	Civil Action No. 1:09-cv-2351-TWT **CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

TABLE OF CONTENTS

Lead Plaintiff the Colleges of Applied Arts and Technology Pension Plan ("CAAT" or "Lead Plaintiff"), by its undersigned counsel, brings the claims set forth herein individually and on behalf of all other persons who purchased or acquired Immucor, Inc. ("Immucor" or the "Company") securities during the period from October 19, 2005, through and including June 25, 2009 (the "Class Period"). The following allegations are based upon the investigation conducted by Lead Plaintiff's counsel, which included, among other things, a review of the public announcements made by the Defendants, filings with the United States Securities and Exchange Commission ("SEC"), press releases, analyst and media reports regarding Immucor, U.S. Food and Drug Administration ("FDA") documents regarding Immucor, interviews with confidential witnesses described herein, and certain other public filings.

I. NATURE OF THE ACTION

1. This is a securities class action brought under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a); and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

II. JURISDICTION AND VENUE

2. This court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa), and 28 U.S.C. § 1331.

3. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. §§ 1391(b) and (c). Substantial acts in furtherance of the wrongs alleged and/or their effects have occurred within this District, and Immucor maintains its principal office in Norcross, Georgia.

4. In connection with the acts and omissions alleged in this Consolidated Amended Class Action Complaint, all of the Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. OVERVIEW OF EXCHANGE ACT VIOLATIONS

5. Immucor, as the largest supplier of blood reagents[1] in the United States, is heavily regulated by the FDA and subject to stringent guidelines for its manufacturing processes. The Company operates under licenses issued by the

[1] Blood reagents are substances designed and manufactured to test, match, detect, screen, diagnose or otherwise identify certain properties of the cell and serum components of human blood.

FDA which can be revoked upon a finding of repeated violations and lack of commitment to quality processes. Accordingly, quality procedures – which are designed to ensure that the Company is in compliance with federal regulations – are critical for Immucor's continuing operations. Indeed, recognizing that in a highly regulated industry, Immucor would be expected to maintain first-rate quality processes, Defendants, throughout the Class Period, assured the market that "[t]he commitment to quality at Immucor is company-wide and we are continually seeking opportunities for improvement." Moreover, in its reports on Form 10-K, filed with the SEC during the Class Period and signed by the Individual Defendants (defined below), Defendants represented that Immucor's "manufacturing and on-going quality control procedures conform to the required statutes, regulations and standards."

6. Nonetheless, throughout the Class Period, Defendants neglected Immucor's quality processes and ignored repeated FDA violations identified both by the FDA and internal quality management. Ultimately, Defendants' flouting of federal law led to the FDA's notice of intent to revoke ("Notice of Intent to Revoke") Immucor's licenses on June 25, 2009, the revocation of which would result in a shutdown of Immucor's major operations.

7. As the FDA made clear, Defendants' complete disregard of quality forced the FDA's hand in issuing the Notice of Intent to Revoke. Of particular concern was the recurring nature of Immucor's violations:

> While these deviations were documented in the most recent inspection, we note that ***similar deviations have been documented in past FDA inspections. The seriousness of these deficiencies have been repeatedly emphasized to you during previous FDA inspections*** of March 7-16, 2006, and January 8-17, 2008, as well as in a Warning Letter dated May 2, 2008.[2]

(Emphasis added unless otherwise stated).

8. The FDA placed the blame for Immucor's lack of quality procedures directly on the Company's management, specifically Defendant Dr. Gioacchino De Chirico ("De Chirico" or "Nino"), the President and CEO of the Company. The FDA asserted that De Chirico "as management with executive responsibility [had] not established a commitment to quality nor ensured that the quality policy is understood, implemented, and maintained at all levels of the organization" in specific violation of federal regulations.

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[2] Warning letters are issued by the FDA for violations of "regulatory significance." Violations of "regulatory significance" are those violations that may lead to enforcement action if not promptly and adequately corrected. Prior to receiving the warning letter, the Company had also received FDA Form 483s following FDA inspections in March 2006 and January 2008. A Form 483 contains observations made by the field investigator that can be directly linked to one or more violations by the establishment.

9. Defendants' blatant disregard of FDA requirements stemmed from a culture of arrogance that fostered the idea that Immucor was too big to shutdown. Because of its status as the largest supplier of blood reagents, a critical, medical product, Defendants believed that the FDA would never revoke the Company's license regardless of the egregious deficiencies in its quality systems or any recurring findings of noncompliance with FDA regulations. According to Confidential Witness No. 1, Immucor's Vice President of Quality from July 2005 to February 2009 ("CW1"),[3] Defendant Ralph A. Eatz ("Eatz"), the Company's Chief Scientific Officer, during a meeting held around the time Immucor received a warning letter from the FDA in May 2008, scoffed at the idea that the FDA would ever revoke Immucor's licenses. He asserted that Immucor was too essential in the immunohematology industry for the FDA to ever have the nerve to shut it down. According to CW1, this attitude was rampant at Immucor during her tenure and, in part, contributed to senior management's disregard of the Company's quality function.

[3] CW1's position as Vice President of Quality included both quality control as well as quality assurance. Quality control ensures that products meet the defined acceptance criteria prior to release while quality assurance covers the more global aspects of the quality system.

10. The "too big to shutdown" mentality leading to the lack of commitment to quality came straight from the top. Defendant De Chirico made clear that quality was a nonessential function of the Company. Indeed, within CW1's first week of employment at Immucor, De Chirico suggested that quality procedures take a back seat to revenues and profits and told CW1, a direct report to De Chirico and the Company's chief quality executive, that "If we don't talk to each other, that's a good thing." Indeed, throughout most of CW1's tenure at the Company, general quality topics were not on the agenda for monthly operational meetings led by De Chirico and attended by the full executive management staff, including CW1.

11. While Defendants relegated quality to the dustbin, Immucor's quality team, throughout the Class Period, continuously noted and reported serious, recurring quality deficiencies to the highest ranks of the Company, in particular Defendant De Chirico and Eatz. According to CW1, these deficiencies were the same type of violations found by the FDA in its inspections that occurred during the Class Period. In particular, Immucor's quality team, as well as the FDA, found that the Company continuously failed to properly conduct "root cause" analyses or investigations, and failed to maintain proper validation processes, issues that are critical to maintaining properly functioning quality procedures.

12. Since the beginning of the Class Period, Defendants were repeatedly warned by internal quality personnel regarding Immucor's lack of compliance with FDA regulations and proper quality protocol. Indeed, throughout the Class Period De Chirico and Eatz received minutes from quarterly metrics meetings that identified these FDA deficiencies with recommendations to fix the problems. These warnings were summarily ignored.

13. As the FDA noted in its Notice of Intent to Revoke, even the violations identified during FDA inspections and discussed in Form 483s which were provided to Defendants were disregarded, including *inter alia*, failure to establish corrective and preventative action in order to prevent or correct the recurrence of nonconforming product (*i.e.*, root cause violations), failures to adequately control environmental conditions, failures to establish and maintain procedures for monitoring parameters for validated processes, and failures to investigate complaints involving Immucor's products.

14. Supplanting all interest in quality procedures and FDA guidelines, Defendants focused all their energy on short-term revenue and profits. Outwardly, Defendants' management of the Company seemed unassailable – commitment to stringent quality procedures, record revenues, record profit. Unbeknownst to the investing public, this perception was false. Not only did Defendants ignore quality

procedures and FDA rules and guidelines, according to CW1, Defendants also refused to expend the necessary funds to ensure compliance with FDA regulations. This refusal surely benefitted Immucor's bottom line in the short run, but the long-term ramifications of such actions were clearly detrimental to the Company.

15. However, the main catalyst for its record growth in revenues and profits was the result of Immucor's illegal conspiracy with its main competitor Ortho-Clinical Diagnostics, Inc. ("Ortho") to raise the prices of traditional blood reagents.[4] Prior to the Class Period, Defendants laid the foundation for a workable antitrust conspiracy by causing Immucor to take on approximately $30 million in debt in order to acquire many of its competitors. At the end of this acquisition spree, Immucor was nearly insolvent but had only one viable competitor, Ortho.

16. Defendants knew that even with one viable competitor, raising prices of Immucor's products by significant levels would be impossible without collusion. According to Confidential Witness 2 ("CW2"), the Director of Sales at Immucor from July 2000 to December 2004, Defendant Edward L. Gallup

[4] Traditional blood reagents are used for the manual testing of blood, where an individual assesses each specimen by hand, one at a time. Most of the blood reagents manufactured and sold by Immucor and Ortho are traditional blood reagents, as opposed to proprietary "automated" blood reagents, which are used in conjunction with the automated blood testing systems each of these two companies also sells.

("Gallup"), the Company's founder, Chairman of the Board of Directors and CEO during the Class Period, specifically requested that CW2 conduct an economic study to determine how much the Company could increase prices of its products. CW2 performed the analysis along with members of the sales team and concluded that the ***most*** Immucor could raise prices without losing customers was 15%. Of course, such a study was based on the premise that Immucor functioned in a competitive market. Presented with this finding, Gallup expressed amusement and claimed that a 15% price increase would be insufficient to increase Immucor's profitability. Just one month later, Ortho announced during a trade association meeting that it would be raising its prices and shortly released a price list raising prices by an astounding 300%. Immucor followed suit and, since that time, both Immucor and Ortho have increased prices of their products in concerted action.

17. As a result of Defendants' disregard for FDA guidelines and federal antitrust laws, Immucor's common stock traded at highly artificial prices to the direct benefit of Defendants De Chirico, Eatz and Gallup.

18. Prior to the implementation of the price fixing conspiracy between Immucor and Ortho, Immucor was in terrible financial condition which was reflected in the price of Immucor's common stock. By the summer of 2000, Immucor's common stock traded at approximately $4 per share. This directly and

negatively affected the Individual Defendants as they held hundreds of thousands of options that were underwater as the strike price for many of these options was over $9.00 per share. Accordingly, these Defendants were highly motivated to increase the price of the Company's common stock. Unsurprisingly, a little over a year after the effective date of the 300% price increase, Immucor's stock price began to rise, and Defendants took full advantage of their stock options which were no longer under water. Defendants sold millions of dollars in Immucor stock beginning in or around the summer of 2002 and continuing throughout the Class Period. In fact, during the Class Period, Defendant De Chirico, sold 222,603 shares of Immucor at artificially inflated prices for proceeds of nearly $6 million. Additionally, Eatz sold 874,399 shares of Immucor stock for proceeds of nearly $25 million, while Gallup sold 503,748 shares of Immucor securities for proceeds of more than $13.2 million. Each of these Defendants' Class Period sales were unusual in that, among other reasons, they represented a sharp departure from their sales prior to the beginning of the undisclosed price fixing conspiracy alleged herein.

19. In the end, Defendants' evasion of federal regulations and statutes caught up with them. As federal regulators opened up formal investigations and commenced potential enforcement actions, Defendants were forced to disclose

Immucor's FDA violations and federal investigations of potential anticompetitive activity causing the price of Immucor's common stock to fall precipitously. On October 26, 2007, as a result of the Company's disclosure of the Federal Trade Commission's (the "FTC") request for documents and information regarding Immucor's acquisitions and the Company's pricing policies since 1996, the price of Immucor's common stock dropped $3.30 per share, a decline of 9.36%. On that date, however, the Company reassured investors by emphasizing the fact that the FTC request specifically stated that the existence of the investigation did not indicate that the Company had violated the law.

20. On April 24, 2009, Immucor announced it had received a subpoena by the United States Department of Justice ("DOJ"), Antitrust Division, for its investigation of possible violations of federal criminal antitrust laws in the blood reagents industry. Once announced, Immucor's stock price plummeted nearly 27%.

21. In addition to discovering that Immucor was embroiled in a criminal antitrust investigation, the market began to learn about Defendants' defiance of FDA regulations. By May 2008, the FDA's findings of repeated and material violations resulted in an FDA warning letter which was disclosed by the Company on May 13, 2008. Immucor's common stock price fell 4.5% in response. Once the

market learned about the warning letter, Defendants commenced damage control. Defendants falsely assured the market that they took the FDA's concerns "very seriously" and were "work[ing] diligently" to resolve the problems identified. Defendant De Chirico also falsely represented on January 19, 2009 that Immucor had a "strong commitment to product quality and quality compliance." Despite these assurances, Defendants continued to neglect quality processes and deficiencies identified by the FDA which resulted in the issuance of the Notice of Intent to Revoke on June 25, 2009. The Company disclosed this fact on June 26, 2009, and the stock price again declined another 14.2% to close at $13.80, significantly lower than the Class Period high of $39.00. Tellingly, as of the date of the filing of this amended complaint, Immucor is the ***only*** company in the United States with an outstanding notice of intent to revoke letter from the Center for Biologics Evaluation and Research, the division of the FDA that regulates vaccines, blood and biologics.

IV. PARTIES

A. Lead Plaintiff

22. On January 15, 2010, the Court entered an order appointing CAAT as Lead Plaintiff in this action.

23. CAAT is a pension fund that has served current and former employees of colleges in the Province of Ontario since 1967. CAAT currently serves more than 31,000 members and has over $4.5 billion in assets. It is headquartered in Toronto, Canada. CAAT's transactions in Immucor throughout the Class Period are attached hereto as Exhibit A.

B. Defendants

1. Immucor

24. Defendant Immucor develops, manufactures and sells a complete line of reagents and automated systems used primarily by hospitals, clinical laboratories and blood banks in a number of tests performed to detect and identify certain properties of the cell and serum components of human blood transfusion. Immucor's stock is traded on the Nasdaq under the symbol BLUD.

2. Gioacchino De Chirico

25. Defendant De Chirico, known throughout the Company as "Nino" currently serves as President and CEO of Immucor. De Chirico has served as President of Immucor since July 2003 and has served as CEO of Immucor since September 7, 2006. Prior to joining Immucor, De Chirico was employed by Ortho, Immucor's competitor and antitrust co-conspirator, as General Manager, Immunocytometry, with worldwide responsibility until 1994.

26. De Chirico's pattern of stock sales was highly unusual. Between 1998 and the spring of 2002, De Chirico did not sell any of his holdings of Immucor common stock. In the summer of 2002, a little over one year after Ortho and Immucor were able to increase prices of its products by an astounding 300%, De Chirco suddenly began to sell his holdings. In fact, between May 2002 and the end of the Class Period, De Chirico sold 465,603 shares of Immucor stock at artificially inflated prices for proceeds of more than $10.8 million. As represented by the stock sales chart in ¶37 below, of the 465,603 shares sold during that time, Defendant De Chirico sold 222,000 shares of Immucor common stock for proceeds of approximately $5.9 million during the Class Period, while he knew or was severely reckless in not knowing of Defendants' antitrust conspiracy and Immucor's serious and ongoing quality issues. Moreover, the vast majority of his sales during the Class Period occurred on July 11, 2007, just prior to the Company's disclosure that it was being investigated by the FTC for anticompetitive behaviors. These sales represented approximately 42% of his holdings of Immucor stock at that time.

27. De Chirico also signed the following documents during the Class Period: (1) Immucor's Form 10-Ks for the fiscal years ending May 31, 2006, May 31, 2007, and May 31, 2008; and (2) Immucor's Form 10-Qs for the fiscal periods

ending August 31, 2006, November 30, 2006, February 28, 2007, August 31, 2007, November 30, 2007, February 29, 2008, August 31, 2008, November 30, 2008 and February 28, 2009.

28. Defendant De Chirico has also flagrantly disregarded securities laws in the past. In fact, during the Class Period, the SEC filed a complaint against De Chirico for violating the Federal Corrupt Practices Act when (in April 2004) he caused Immucor to make a cash payment to a physician in Italy in exchange for a favorable contract award. The SEC ordered Defendant De Chirico to pay a penalty and he consented to the entry of a cease and desist order from causing future Exchange Act violations.

29. Also, during the Class Period, Defendant De Chirico was sentenced to a two to three year prison term by a criminal court in Milan Italy in connection with bribery charges related to the payments he unlawfully made to physicians in Italy. The sentence was issued by the Italian court during the first level proceedings and the trial proceeded against De Chirico to a second phase.

3. Ralph A. Eatz

30. Defendant Eatz served as Immucor's Senior Vice President and Chief Scientific Officer during the Class Period and has worked at Immucor since the Company was founded in 1982.

31. Eatz's pattern of stock sales was highly unusual. Like De Chirico, from 1998 and prior to the summer of 2002, Eatz did not sell any of his holdings in Immucor common stock. Beginning in June 2002, Eatz sold substantial amounts of common stock for millions of dollars in proceeds. In fact, between June 2002 (around the time the Company's antitrust conspiracy began to become effective resulting in increased reported revenues and increase in the Company's common stock price) and the end of the Class Period, Eatz sold 1,204,099 shares of Immucor stock for proceeds of over $32.4 million, including sales of 874,399 shares during the Class Period, reaping proceeds of nearly $25 million while he knew of or was severely reckless in not knowing of Immucor's serious and ongoing quality issues as well as the Company's ongoing antitrust conspiracy. In addition, from the beginning until the end of the Class Period, Eatz decreased his holdings in Immucor common stock by approximately 40%.

32. Eatz also signed the following documents during the Class Period: (1) Immucor's Form 10-Ks for the fiscal years ending May 31, 2006, May 31, 2007 and May 31, 2008.

4. Edward L. Gallup

33. Defendant Gallup founded Immucor in 1982 and served as CEO and Chairman of the Board of Directors from the beginning of the Class Period until his retirement from the Company effective September 7, 2006. Gallup remained employed by Immucor following his retirement and in March 2007, Immucor entered into a consulting agreement with Gallup.

34. Predictably, Gallup's pattern of stock sales was similar to the other Individual Defendants. Between 1998 and May 2002, he only sold 2,000 shares of Immucor common stock. Then, again, like De Chirico and Eatz, between June 2002 (around the time the 300% price increase begins to effect the Company's profit margins, and thus stock price) and the end of the Class Period, Gallup sold 904,948 shares of Immucor common stock for proceeds of more than $23.3 million. Of the 904,948 shares Gallup sold during that period, as reflected by the chart included below in ¶37, Gallup sold 503,748 shares of Immucor common stock for proceeds of more than $13.2 million during the Class Period, while he

knew or was severely reckless in not knowing of Immucor's serious and ongoing quality issues as well as the Company's ongoing antitrust conspiracy.

35. Gallup signed the following documents during the Class Period: (1) Immucor's Form 10-Ks for the fiscal years ending May 31, 2005 and May 31, 2006; and (2) Immucor's Form 10-Qs for the fiscal periods ending August 31, 2005, November 30, 2005, and February 28, 2006.

36. The Defendants referred to in ¶¶25-35 are collectively referred to as "Individual Defendants".

37. The chart below represents the Individual Defendants' stock sales during the Class Period:

Immucor, Inc. (BLUD) - Insider Sales of Individual Defendants During the Class Period				
Individual Defendant	***Transaction Date***	***Number of Shares***	***Price per Share***	***Total Proceeds***
De Chirico, Gioacchino	06/06/07	732	$29.17	$21,352.44
De Chirico, Gioacchino	07/11/07	221,871	$26.73	$5,930,611.83
TOTAL		**222,603**		**$5,951,964.27**

Immucor, Inc. (BLUD) - Insider Sales of Individual Defendants During the Class Period				
Individual Defendant	***Transaction Date***	***Number of Shares***	***Price per Share***	***Total Proceeds***
Eatz, Ralph A	10/11/06	64,186	$26.06	$1,672,687.16
Eatz, Ralph A	10/11/06	64,186	$26.06	$1,672,687.16
Eatz, Ralph A	10/12/06	5,700	$26.26	$149,682.00
Eatz, Ralph A	10/13/06	30,114	$26.11	$786,276.54
Eatz, Ralph A	10/16/06	44,369	$26.52	$1,176,665.88
Eatz, Ralph A	10/19/06	105,631	$26.39	$2,787,602.09
Eatz, Ralph A	10/26/06	50,000	$26.52	$1,326,000.00
Eatz, Ralph A	06/06/07	665	$29.17	$19,398.05
Eatz, Ralph A	07/27/07	74,548	$32.50	$2,422,810.00
Eatz, Ralph A	07/30/07	25,000	$31.11	$777,750.00
Eatz, Ralph A	07/31/07	50,000	$31.39	$1,569,500.00
Eatz, Ralph A	08/02/07	50,000	$32.07	$1,603,500.00
Eatz, Ralph A	08/03/07	50,000	$31.79	$1,589,500.00
Eatz, Ralph A	08/08/07	100,000	$31.89	$3,189,000.00
Eatz, Ralph A	11/04/08	10,000	$27.31	$273,100.00
Eatz, Ralph A	11/11/08	10,000	$26.36	$263,600.00
Eatz, Ralph A	11/18/08	10,000	$25.00	$250,000.00
Eatz, Ralph A	12/18/08	10,000	$25.00	$250,000.00
Eatz, Ralph A	12/30/08	10,000	$25.00	$250,000.00
Eatz, Ralph A	01/06/09	10,000	$25.16	$251,600.00
Eatz, Ralph A	01/13/09	10,000	$26.81	$268,100.00
Eatz, Ralph A	01/20/09	10,000	$27.67	$276,700.00
Eatz, Ralph A	01/27/09	10,000	$28.01	$280,100.00
Eatz, Ralph A	02/03/09	10,000	$27.97	$279,700.00
Eatz, Ralph A	02/10/09	10,000	$27.67	$276,700.00
Eatz, Ralph A	02/17/09	10,000	$26.98	$269,800.00
Eatz, Ralph A	02/24/09	10,000	$25.12	$251,200.00
Eatz, Ralph A	03/24/09	10,000	$25.08	$250,800.00
Eatz, Ralph A	03/31/09	10,000	$25.00	$250,000.00
Eatz, Ralph A	04/07/09	10,000	$25.95	$259,500.00
TOTAL		**874,399**		**$24,943,958.88**

Immucor, Inc. (BLUD) - Insider Sales of Individual Defendants During the Class Period				
Individual Defendant	***Transaction Date***	***Number of Shares***	***Price per Share***	***Total Proceeds***
Gallup, Edward L	10/16/06	189,843	$26.33	$4,998,566.19
Gallup, Edward L	10/20/06	303,905	$26.15	$7,947,115.75
Gallup, Edward L	10/23/06	10,000	$26.00	$260,000.00
TOTAL		**503,748**		**$13,205,681.94**

V. DEFENDANTS' DISREGARD OF FDA REGULATIONS AND VIOLATIONS OF U.S. ANTITRUST LAWS

A. Immucor Is Heavily Regulated by the FDA

38. Immucor operates in a heavily regulated industry. As Immucor itself has acknowledged, "all phases" of its business are regulated by the FDA, and the Company relies on facility and product licenses issued by the FDA for its operations in the United States. Without the FDA's stamp of approval, Immucor cannot manufacture and sell its products in the United States.

39. In order to maintain its FDA licenses, Immucor must pass regular and unannounced plant and facility inspections by the FDA. To the extent the agency finds repeated violations and lack of commitment to quality – a function designed to ensure that the Company is in compliance with federal regulations – the FDA can revoke Immucor's licenses. Accordingly, quality procedures are fundamental to Immucor's business.

40. Nonetheless, as detailed herein, throughout the Class Period, Defendants ignored Immucor's quality function and managed the Company as if it was exempt from FDA regulations. This blatant disregard for FDA rules and guidelines ultimately led to the agency's Notice of Intent to Revoke Immucor's licenses with respect to two of the Company's most important products.

B. Lack of Commitment to Quality Control Pervades Immucor's Corporate Culture

41. Immucor's complete disregard for quality came from the top. According to Confidential Witness 3 ("CW3"), Immucor's Vice President, Worldwide Operations from 2000 until January 2008 and a direct report to Defendant De Chirico, De Chirico did not consider quality a priority and, during CW3's tenure at the Company, Immucor had "substandard" quality procedures.[5]

42. This lack of commitment to quality was also witnessed by CW1, Immucor's Vice President of Quality during the Class Period. CW1's general assessment upon arriving at Immucor in July 2005 was that there were significant issues in the quality department and that quality was considered a nonessential function at the Company. Indeed, within the first week of CW1's employment at

[5] CW3, as Vice President of Operations, was responsible for the oversight of Immucor's production operations including product manufacturing, packaging operations, facility engineering and supply chain management. CW3 also participated in the FDA inspections.

Immucor, De Chirico made clear his opinion about the Company's quality function. Defendant De Chirico, during their initial conversations, told CW1 that "if we don't talk to each other, that's a good thing," a remarkable directive considering that CW1, the head of quality at the Company, reported directly to De Chirico.

43. John Adair ("Adair"), who served as Vice President of World Wide Quality at Immucor from 2001 until 2005, was confronted with the same lack of commitment to quality which ultimately led to his dismissal. According to CW3, Adair was terminated because of his criticisms that De Chirico's myopic focus on revenues was materially undermining quality at the Company. In fact, according to CW3, Defendants' complete lack of interest in quality led to high turnover rates in Immucor's quality department leading to further weakening of the quality function at the Company.

44. Even prior to the Class Period, and during John Adair's tenure at Immucor, Defendants' lack of commitment to quality was pervasive. According to CW2, during his tenure at Immucor from 2000 until 2004, there were serious quality deficiencies at Immucor but Defendants were not willing to spend the necessary funds to resolve these issues because top management believed Immucor was too big a player in the market for the FDA to ever shut the Company down.

The lack of attention to quality is perhaps best demonstrated by the fact that despite serious quality issues, according to CW1, at that time, there was a significant reduction in headcount of quality positions, which had a negative effect on Immucor's quality policies and procedures.

45. According to CW1, even during monthly executive staff meetings, held to discuss the important operations of the Company, general quality issues were not on the agenda. These monthly meetings often occurred on the third Friday of every month and were specifically headed by Defendant De Chirico.

46. Faced with this corporate mindset instilled by Defendants, quality personnel were unable to institute a quality function that would ensure the Company's compliance with FDA regulations. Warnings by internal quality personnel about Immucor's lack of proper quality procedures and violations of FDA regulations fell on deaf ears because, according to CW1, Defendants believed that the FDA would never shut down Immucor's operations – an attitude that was also prevalent prior to the Class Period as indicated by CW2. This sentiment was crystallized by Defendant Eatz, the Company's Chief Scientific Officer, when at approximately the time the Company received a warning letter from the FDA in May 2008, he scoffed at the idea that the FDA would ever revoke Immucor's

license and asserted that Immucor's importance in the immunohematology industry would make it impossible for the FDA to shut it down.

47. Defendants' dismissal of the quality function at Immucor and their failure to establish a commitment to quality was contrary to FDA regulations, specifically 21 C.F.R. §820.20(a) (2010).[6] This critically important regulatory provision provides that "Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality."

C. Defendants Are Acutely Aware of Immucor's Failure to Comply with FDA Regulations

48. Throughout the Class Period, Defendants were repeatedly warned by Immucor's quality executives that the Company was not in compliance with FDA regulations. Indeed, CW1, throughout her tenure at Immucor, attended quarterly metrics meetings during which time quality deficiencies and FDA violations at the Company were identified and discussed, and minutes of these meetings were provided to Defendants De Chirico and Eatz.

49. According to CW1, the minutes from metric meetings provided to Defendant De Chirico and Eatz during the Class Period repeatedly identified the same types of deficiencies that the FDA found during its inspections in 2006, 2008

[6] Although the citations to the Code of Federal Regulations herein are to regulations in effect as of 2010, these identical regulations were also effective during the Class Period.

and 2009. For example, in the beginning of the Class Period, the metric meeting minutes outlined the Company's inadequate policies concerning root cause investigations in violation of 21 C.F.R. §820.100 (2010), as well as failures to properly conduct validation/qualification studies in violation of 21 C.F.R. §820.75(b) (2010).

50. Then, during the FDA inspection between March 7 through 16, 2006, the FDA found thirteen types of FDA violations, including, *inter alia*, inadequate policies and practices regarding complaints and Medical Device Reports ("MDR") in violation of 21 C.F.R. §198 (2010) and 21 C.F.R. §803.50(a)(2) (2010), failure to report changes to approved license applications in violation of 21 C.F.R. §820.70 (2010), failure to conduct root cause investigation in violation of 21 C.F.R. §820.100, and failure to conduct proper validation/qualification studies in violation of 21 C.F.R. §820.75(b).[7] As the FDA noted, there were numerous incidents of each of these violations that had occurred during Immucor's 2005 fiscal year ending May 31, 2005. For instance, the FDA found a total of ***seven*** incidents occurring on March 25, 2005; April 8, 2005; April 28, 2005; August 29,

[7] The term "validation" refers to the process whereby a company ensures that it is manufacturing its products pursuant to particular specifications. Similarly, the term "qualification" refers to the process whereby a company ensures its equipment operates pursuant to particular specifications. The terms validation and qualification are often used interchangeably.

2005; October 24, 2005; October 25, 2005; and February 9, 2006, where Immucor failed to conduct or complete root cause investigations.

51. FDA guidelines require root cause investigations so that a company is able to determine the cause of a particular violation. To avoid future violations, once the cause is found, a root cause analysis requires the company to formulate a remedy. One example of an improper root cause investigation that occurred on or about February 9, 2006, was the Company's investigation of a product manufacturing problem. The FDA found that Immucor had identified the cause of the problem as glass particles partially blocking a line, but did not complete the investigation because the Company failed to investigate where the glass particles came from and what measures could be taken to prevent recurrence.

52. With respect to the Company's failure to submit MDRs, a violation of 21 C.F.R. §803.50(a)(2), the FDA found that the Company had received numerous customer complaints about Immucor's products beginning at least as early as June 2005, including product malfunctions with respect to the Company's Galileo automated blood grouping instrument and complaints pertaining to the Company's Blood Grouping Reagent, Anti-e Series 1 (Monoclonal). Despite having received such reports, the FDA noted that the Company failed to report these occurrences to the FDA.

53. All the deficiencies found during the 2006 FDA inspection were communicated to Immucor at the close-out meeting held by the FDA at the close of the inspection. According to the FDA Establishment Inspection Report for the March 2006 inspection, Eatz attended this meeting. CW1, who was also present at the close-out meeting, maintained that the types of deficiencies the FDA had identified were "numerous and repeat issues" that had been identified by Immucor's quality department and communicated to Defendants DeChirico and Eatz, through minutes of the quarterly metric meetings, among other things, on numerous, previous occasions.

54. Despite the FDA's findings of noncompliance with federal regulations, Defendants falsely claimed that Immucor's "manufacturing and on-going quality control procedures conform[ed] to the required statutes, regulations and standards." In addition, following the March 2006 inspection, Defendants falsely represented that they were actively addressing the problems identified during the FDA's 2006 inspection, which they merely discussed as "observations" and "implement[ing] corrective actions" to address these observations. However, according to CW1 and, indeed, the FDA itself, Immucor failed to remedy the material objectionable conditions identified by the FDA and internal quality management.

55. Furthermore, in or around October 5, 2006, in a conference call with investors, Defendant De Chirico touted a new Immucor product called "whole blood control" which he claimed was a "breakthrough" way to perform quality control. Defendants failed to disclose, however, that according to CW1, this product was riddled with manufacturing deficiencies, problems which were outlined in the quarterly metrics minutes and provided to De Chirico and Eatz. Furthermore, De Chirico's statement exemplifies the misleading impression Defendants provided to Immucor investors of Defendants' commitment to quality.

56. Immucor's assertion that the Company was "implement[ing] corrective actions" with respect to the deficiencies found by the FDA during the 2006 inspection is further belied by the FDA's findings in January 2008. Between January 8 and January 17, 2008, the FDA conducted another inspection of Immucor's Norcross facility. Incredibly, the FDA found the same types of violations that it had identified in 2006 – again, the same types of violations that, according to CW1, were discussed and outlined during the quarterly metric meetings. As the FDA recognized in its 2008 inspection report, the violations the FDA found in 2008 demonstrated "***continuing*** [good manufacturing practice] deficiencies" from the agency's prior 2006 inspection. The fact that Immucor had been found to have continuing violations were not disclosed at this time.

57. Again, the FDA cited Immucor for, among other things, failure to conduct adequate root cause investigations in violation of 21 C.F.R. §820.100, inadequate policies and procedures concerning MDRs in violation of 21 C.F.R. §803.50(a)(2), failing to conduct "validation/qualification studies of processes, equipment and test methods" in violation of 21 C.F.R. §820.75(b), and "failure to establish and maintain procedures for changes to a specification, method, process, or procedure" in violation of 21 C.F.R. §820.70. As the reportable incidents identified during the 2008 inspections demonstrate, Immucor, more than a year after being cited by the FDA for inadequate controls, had not remedied the control deficiencies at the Company. For example between November 12, 2007 and December 5, 2007, Immucor received numerous complaints about a product. The Company found that the complaints were "reproduced, but not confirmed" but, as the FDA criticized, the root cause for the adverse trend was not investigated, demonstrating the falsity of Defendants' statement after the 2006 inspection that Immucor was actively addressing problems identified by the FDA and "implementing corrective action".

58. Another incident of a root cause problem identified by the FDA occurred in November 2006, weeks prior to the close of the second fiscal quarter 2007. Around that time, a number of complaints had been received by the

Company concerning non-conforming products, including for example yeast contamination. According to the FDA, these complaints were not properly investigated. In addition, there was at least one incident where an investigation was not performed for a product that had been recalled. According to the FDA Establishment Inspection Report for the January 2008 inspection, Defendant De Chirico was present at the close-out meeting where the FDA's findings were discussed.

59. The FDA findings were no surprise to the Company's quality management. According to CW1, internal quality personnel continuously reported root cause and validation violations to top executives, De Chirico and Eatz in particular. Indeed, CW1 witnessed other egregious violations that occurred within months of the January 2008 inspection.

60. For example, according to CW1, in October 2007, Tama Copeland, the Company's Director of Red Blood Cell Manufacturing, violated standard operating procedures and FDA regulations for investigative reports. Under Immucor's procedure for investigative reports, employees are tasked with inputting the relevant information for an investigative report in the system. In order to create the investigative report, employees must use personally issued passwords before being allowed to input the information into the system. This information is then

reviewed and approved by management, including Ms. Copeland. Once reviewed and approved, the investigative report would be forwarded to the quality department. The purpose of this procedure, *i.e.*, one employee drafting the investigative report and management reviewing and approving the investigative report, was to ensure the accuracy of such reports. Ms. Copeland circumvented this mandated process, obtained the passwords of lower level employees, and improperly used these passwords to generate an investigative report. She then approved the report in her management capacity, a blatant violation of FDA regulations.

61. The Director of Quality reported Ms. Copeland's improper conduct to CW1. CW1 reported the incident to CW3 who then reported it directly to Defendant De Chirico. An investigation was conducted but, despite her expertise regarding quality procedures, CW1 was removed from the investigation.

62. Moreover, amazingly, during the January 2008 inspection itself, Immucor was falsifying quality reports. CW1, who was closely involved with the January 2008 inspection, stated that FDA requested temperature records for review. However, in violation of FDA regulations, these records were only partially complete. Accordingly, the Immucor employees involved in the

inspection falsified these records by making up historic temperature data and provided those falsified records to the FDA.

63. After the disastrous January 2008 FDA inspection, Immucor again promised the FDA that it would engage in "corrective action" to remedy the problems. These "corrective actions" were detailed in letters to the FDA which the FDA found unsatisfactory. In response to Immucor's written submissions, the FDA issued a warning letter on May 2, 2008 directed to Defendant De Chirico chastising Immucor for failing to "provide sufficient detail to fully assess the adequacy of [Immucor's] corrective actions." Among other things, the "responses fail[ed] to discuss implementation of adequate quality assurance oversight to ensure prompt identification, correction, and follow up to problems associated with the manufacture of [Immucor's] products."

64. After receiving the warning letter and to ease investors' concerns, Defendants falsely claimed that Immucor took its "regulatory responsibilities very seriously and [was] working diligently to respond to the FDA." Despite these assurances, Defendants continued to place quality issues on the back burner. The reason was clear; Defendants believed that Immucor was too important a player in the industry for the FDA to shut it down. In fact, Defendant Eatz directly

expressed this sentiment to CW1 around the time Immucor received the warning letter.

65. From January 6 through January 16, 2009, the FDA conducted a subsequent inspection of Immucor's Norcross facility and found that the violations cited in the January 2008 and the March 2006 inspections had still yet to be resolved. These recurring quality control deficiencies included: (1) failure to properly conduct root cause investigations in violation of 21 C.F.R. §820.100; (2) validation/qualification studies of processes, equipment and test methods were not always conducted or were incomplete in violation of 21 C.F.R. §820.75(b); (3) a number of violations of complaint handling procedures, which is a violation of 21 C.F.R. §820.198; and (4) failures concerning Immucor's "production and process controls", which is a violation of 21 C.F.R. §820.70.

66. In fact, with respect to the root cause condition, the FDA noted in its Form 483 that there was a "substantial increase in contamination events since the FDA inspection in January 2008" and that as a result of these failures "repeat failures are encountered." Following the inspection, Defendant De Chirico received the Form 483 identifying eleven objectionable observations.

67. The Form 483 confirmed that not only had conditions not improved at Immucor, but in fact had gotten worse. In addition to the recurring deficiencies

dating back to the March 2006 inspection identified above, the FDA also noted additional violations including the shipping of products prior to completion of "out of specification [(OOS)] testing and/or OOS failure investigations." With respect to this problem, the FDA noted that this was a repeat failure from the January 2008 inspection. Additionally, the FDA stated that there hundreds of complaints in the Company's complaint database concerning product contamination.

68. Defendants did not begin to disclose the FDA findings of material noncompliance following the January 2009 inspection until April 7, 2009 during a conference call. With respect to the FDA findings, Defendant Gallup explained: "We recognize that our progress in improving our quality processes and systems needs to be faster than we could accomplish using our internal resources alone . . ." However, according to Confidential Witness 4 ("CW4"), the Product Manager at Immucor's Norcross Facility from October 2008 until April 2009, Defendants did not take the prior deficiencies identified by the FDA seriously, and there was no effort to resolve the quality issues that had been identified during the January 2009 inspection.[8]

[8] CW4 worked on the production side at Immucor's Norcross facility, managing the second shift operation for packaging of reagents.

69. As a result of Defendants' failure to demonstrate the necessary commitment to quality, following the January 2009 inspection, the FDA, on June 25, 2009, issued the Notice of Intent to Revoke, which was addressed to Defendant De Chirico, informing the Company that its "manufacture of Reagent Red Blood Cells and Anti-E (Monoclonal) Blood Grouping Reagent product fail to conform to the applicable standards established in your license."

70. The Notice of Intent to Revoke explicitly held De Chirico accountable for the deficiencies identified by the FDA and stated that "[y]ou as management with executive responsibility have not established a commitment to quality nor ensured that the quality policy is understood, implemented, and maintained at all levels of the organization," as required by federal regulations. The FDA chastised management at Immucor for failing to "exercise control in all matters in relation to compliance with the federal regulations and the standards in your license." Furthermore, the letter stated that "unless [Immucor] demonstrate[s] or achieve[s] compliance with the applicable standards and regulations, it is the intent of the FDA to institute proceedings to revoke the biologics license with respect to [its] Reagent Red Blood Cells and [its] Anti-E (Monoclonal) Blood Grouping Reagent product." These two products represented a significant amount of the Company's

operating income and revenues (approximately 30% of operating income and 25% of revenues).

71. Although Immucor assured the FDA that it would take immediate remedial action to correct the deficiencies repeatedly found by the FDA, the FDA dismissed those assurances noting that Immucor "repeatedly promised such corrective actions in the past, but follow-up inspections continue[d] to demonstrate that adequate, effective, and long term corrective action ha[d] not been taken."

72. Indeed, one of the significant problems identified in the Notice of Intent to Revoke can be tied directly to a type of violation that was consistently a topic of the quarterly metric reports throughout the Class Period – failure to conduct root cause investigations. The Notice of Intent to Revoke identified a microbial contamination of Immucor's products and Immucor's failure to properly investigate the problem and failing to identify the ***root cause*** of the contamination. According to CW1, the problem identified in the Notice of Intent to Revoke, which pertained to a massive yeast contamination problem of several Immucor products and several lots of products that Immucor had failed to identify or correct prior to shipping, was not surprising given that De Chirico and Eatz ignored quality and, despite being warned time and time again, failed to conduct proper root cause investigations.

D. Defendants Disregard Quality for Revenues and Growth

73. According to CW1, the Company, at the direction of De Chirico, sacrificed quality issues to improve the bottom line. Defendants would not spend the funds needed to establish quality controls and procedures that would ensure compliance with FDA regulations.

74. It was not until very late in the Class Period, after the FDA's January 2009 inspection that found Immucor had utterly failed to address problems that the FDA had cited as far back as March 2006, that Defendants began to spend much needed capital on quality improvement. On April 7, 2009, during a conference call, Defendant Gallup continued to assure investors that Immucor took its "regulatory responsibility very seriously and implemented a remediation plan to address the FDA findings." Gallup further stated that Immucor planned to spend between $1.5 million and $2 million in the fourth quarter ended May 31, 2009 for Immucor's alleged quality process improvement. This amount was further increased to $6 to 7 million in the fiscal year 2010, an amount that, if spent at the beginning of the Class Period, would have increased the Company's operating expenses for fiscal year 2005 by 12-14%.

E. Defendants' Focus on Revenues And Growth Lead to Violations of Federal Law

75. On April 24, 2009, Immucor announced that the DOJ had commenced a criminal investigation into possible antitrust conspiracy between Immucor and Ortho, Immucor's largest competitor, to fix prices of blood reagent products. The genesis of this price fixing activity, the results of which would squarely fit with Defendants' emphasis on revenue and income growth at the expense of sound management practices, started in early 2000 and continued during the Class Period. Unknown to investors, throughout the Class Period, Immucor's price fixing activities was the primary driver of the dramatic increases in the Company's revenues.

1. Genesis of the Antitrust Conspiracy

76. Prior to the Class Period (in the mid to late 1990s) the blood reagent industry was highly competitive. According to CW2, during this period there were approximately five competitors in the market for blood reagents, a commodity product.

77. In 1994, Defendant De Chirico joined Immucor after leaving Ortho. Shortly thereafter, Immucor embarked on a campaign to eliminate competition in the blood reagents industry by acquiring a number of its competitors. In order to do so, Immucor borrowed approximately $30 million. According to CW2, by the

summer of 2000, Defendants' acquisition spree placed the Company in an untenable position. Immucor was on the verge of collapse from the mountain of debt it had taken on and was in violation of debt convenants. The Company's stock price had plummeted and stock options which had been granted to Defendants De Chirico, Eatz and Gallup were under water.[9]

78. In order to prop up the Company' stock price, Defendants Gallup, Eatz and De Chirico commenced a roadshow espousing the Company's consolidation strategy. They also claimed that investors would see a significant increase in revenues as a result of an increase in prices. Publicly, they assured investors that they were adopting pricing strategies, in essence, to increase prices of their products. In July 2000, Defendant Gallup stated: "We are in the process of realigning prices in North America to better cover the cost of producing our products and to more fully recogni[z]e the value [of] these products."

79. Although Immucor's acquisition strategy had placed the Company deeply in debt, it primed the industry for collusion. As a result of Immucor's acquisition spree, Ortho (De Chirico's former employer) was the Company's only viable competitor. In this environment, in the fall of 2000, Defendant Gallup

[9] At or around this time such options could be exercised at more than $9 per share while the Company's common stock price was trading for less than $4 per share.

asked CW2 to prepare an analysis about the plausibility of price increases. CW2 and the sales team studied the situation, and based on demand in a competitive market, they concluded that Immucor could increase prices by 15% without risk of losing customers to Ortho. Defendants De Chirico and Gallup dismissed their findings with amusement.

80. Shortly thereafter, in the fall of 2000, at the annual conference of the American Association of Blood Banks, Ortho conducted a presentation and announced significant upcoming price increases.

81. In December 2000, Immucor received Ortho's pricing list which reflected a 300% price increase – a stark contrast to Immucor's own internal study that in a competitive market prices could only be increased by 15% – effective February/March 2001. In fact, according to CW2, as a result of De Chirico's friendly relationship and former contacts at Ortho, Ortho had ensured that Immucor received its pricing list in advance of its price increase. Not surprisingly, Immucor matched Ortho's price increase.

82. According to Confidential Witness 5 ("CW5"), a sales employee at the Company from 1999 until 2003, the sales division was informed by management that Immucor was planning to adjust prices prior to the announcement by Ortho. "There was a sales meeting, and there was a message given to me and

all the sales people. They said: 'We've operated in the red for X number of quarters. We're losing money every quarter. There's gonna be significant adjustments in pricing.'" When the 300% increase was announced, according to CW5, the sales division was floored. "The salespeople almost had heart attacks when we heard the pricing. It wasn't an adjustment. This was several hundred percent."

83. Subsequently, there were simultaneous, substantially similar price increases by Immucor and Ortho throughout the Class Period. For example, in late 2004, Immucor and Ortho raised the prices of a variety of blood reagents in ranges from 87% to as much 254%. Then, in November 2005, Immucor and Ortho increased prices of blood reagents in ranges from 24-42% and in April 2008, Immucor and Ortho raised prices in ranges from 50-100%.

84. These collusive price increases directly resulted in substantial increased profit margins for Immucor. For example, in Immucor's 2001 fiscal year, the profit margin for sales of traditional blood reagents (as a percentage of sales) was approximately 45%. Then, by 2008, the profit margin had increased to 78%. Immucor's ability to increase its profit margins so dramatically without losing market share is not consistent with free competition. Typically, as profit

margins increase, so does the opportunity for one competitor to undercut another's pricing, however that did not occur here.

2. Additional Evidence of an Antitrust Conspiracy

85. Not only is the antitrust conspiracy supported by Immucor and Ortho's ability to dramatically increase the prices for a commodity product by 300% and to continue implementing parallel price increases throughout the Class Period, but the structure of the blood reagent market generally and additional concerted action between Immucor and Ortho, further demonstrates the existence of an antitrust conspiracy.

a. Immucor and Ortho Both Cancel GPO Contracts in Order to Increase Prices

86. Immucor and Ortho, as part of their conspiracy, both took the unusual step of canceling contracts with two of the nation's largest group purchasing organizations ("GPO") in order to raise prices of their blood reagents. GPOs had direct communications regarding prices with upper management at Immucor.

87. According to CW2, sometime in September 2004, Immucor demanded that Premier and Novation (both large GPOs) agree to an average price increase of 105-110% for its blood reagents products. Premier and Novation refused to agree to the increase.

88. In Immucor's 2005 10-K (defined below), Immucor disclosed that it had cancelled these two contracts as part of a new "pricing structure":

> On December 9, 2004, the Company announced the cancellation of its contracts with two of its purchasing groups — Novation and Premier — effective January 10, 2005 and January 26, 2005 respectively. In conjunction with these cancellations, a new tier standardized pricing structure was launched and was applicable to all customers who were not members of group purchasing organizations (including former Novation and Premier customers).
>
> …
>
> These cancellations were undertaken for the purpose of increasing prices to the members of each group which occurred simultaneously with each cancellation. These groups contribute approximately $24.9 million in revenues to Immucor annually.

89. According to CW2, also in September 2004, Ortho similarly demanded that Premier agree to an average price increase of 110% for its blood reagent products. Like Immucor, when Premier refused to agree to the price increase, it canceled the contract. In December 2004, Ortho stated that it had also cancelled the contract in order to increase prices, just as Immucor had done.

90. In a competitive market, free of collusion, these GPOs should have had the leverage necessary to avoid or at least minimize Immucor and Ortho's non-negotiable price increases. It was highly unusual that both of these entities made nearly simultaneous demands, and then invoked each of their respective cancellation clauses in order to raise prices.

b. The Industry in which Immucor Operates is Highly Concentrated

91. When an industry has a high degree of concentration, as has been the case for the blood reagents industry since 2000, it is easier to coordinate behavior among and between co-conspirators and more difficult for customers to avoid the effects of collusive behavior. The Herfindahl-Hirschman Index ("HHI") is a widely-accepted measure of industry concentration which is often used by economists to quantify the degree of market concentration. HHI is calculated by summing the squares of companies' individual market shares within an industry. The DOJ considers an HHI higher than 1800 to be a highly concentrated market.

92. Throughout the Class Period, Immucor and Ortho operated essentially a duopoly, controlling virtually all blood reagent sales in the U.S. Immucor controlled approximately 54% of this market while Ortho controlled approximately 46% of the market. Thus, the HHI for the blood reagents market was nearly 5032. This figure indicates that the blood reagents market is extremely concentrated and therefore highly susceptible to collusion by these two manufacturers.

c. Immucor and Ortho are Both Subjects of Government Investigations

93. On October 26, 2007, Immucor announced that the FTC was investigating the Company concerning whether the Company had "violated federal

antitrust laws or engaged in unfair methods of competition through three acquisitions made in the period from 1996 through 1999, and whether Immucor or others engaged in unfair methods of competition by restricting price competition." Then, in July 2008, the FTC's initial investigation was upgraded to a formal investigation.

94. On April 24, 2009, Immucor announced that the antitrust division of the DOJ had opened a criminal grand jury into its pricing conduct in the blood reagents market.

95. On May 5, 2009, J&J disclosed that in April 2009, Ortho had also "received a grand jury subpoena from the DOJ, Antitrust Division, requesting documents and information for the period beginning September 1, 2000 through the present, pertaining to an investigation of alleged violations of the antitrust laws in the blood reagents industry."

96. The FTC does not have the authority to pursue criminal penalties against antitrust violators and must refer cases involving criminal activity to the DOJ. Thus, it is significant that the DOJ is now investigating Immucor's anticompetitive behavior.

97. The fact that Immucor's and Ortho's behaviors are the subject of a criminal grand jury investigation by the DOJ is also significant because in order to

institute a grand jury investigation, a DOJ Antitrust Division attorney must believe that an actual crime has been committed and prepare a detailed memorandum to that effect. According to the Antitrust Grand Jury Practice Manual if a "Division attorney believes that a criminal violation of the antitrust laws has occurred, he should prepare a memorandum requesting authority to conduct a grand jury investigation." Following a review of that memorandum, the request for a grand jury must be approved by the assistant attorney general for the antitrust division based on the standard that a criminal violation may have occurred.

d. Inter-Competitive Hiring between Immucor and Ortho

98. As discussed above, Defendant De Chirico moved from a senior position at Ortho to being president of Immucor's Italian subsidiary (Immucor Italia, S.r.l. from February 1994 to 1998).

99. In addition to Defendant De Chirico, Hiroshi Hoketsu moved from a senior position at Ortho (he served as President of Ortho-Clinical Diagnostics, K.K. in Japan from 1981 until his retirement in 2002) to Immucor in 2005. Mr. Hoketsu joined Immucor's Board of Directors in April 2005 and continued to serve on Immucor's Board of Directors until the end of the Class Period, June 2009.

100. The movement of these senior executives between Ortho and Immucor heightens the potential for discussions, communications or meetings

between individuals at the two companies, including discussions concerning engaging in collusive anticompetitive behavior.

F. Individual Defendants Profit from Unusual Stock Transactions in Amount and in Timing During the Class Period and Following the Effective Date of the Antitrust Conspiracy

101. During the Class Period, as represented by the chart included in ¶37 above, the Individual Defendants engaged in stock sales resulting in over $44 million in proceeds. In addition, the Individual Defendants collectively reaped more than $66.6 million in proceeds since the beginning of the effective date of the antitrust conspiracy alleged herein. The Individual Defendants' stock sales were highly unusual in nature, both in amount and in timing, because among other reasons, their sales prior to the summer of 2002, a little over one year after the agreed upon 300% price increase, were nonexistent or *de minimis*.

102. From 1998 through April 2002, De Chirico did not sell any Immucor common stock. Then, between May 2002 (around the time the 300% price increase begins to effect the Company's profit margins and its stock price) and the end of the Class Period, De Chirico sold 465,603 shares of Immucor stock for proceeds of more than $10.8 million. As represented by the stock sales chart in ¶37 above, of the 465,603 shares sold during that period, Defendant De Chirico sold 222,000 shares of Immucor common stock for proceeds of approximately $5.9

million during the Class Period in two separate transactions[10] in the summer of 2007, which was shortly before Immucor announced it was under investigation by the FTC. These sales during the Class Period represented 42% of De Chirico's holdings at the time of the transactions, while he was well aware of the antitrust as well as the quality issues at Immucor and the FDA's findings of substantial noncompliance during the March 2006 inspection.

103. Between 1998 and May 2002, Defendant Eatz did not sell any Immucor common stock. Then, between June 2002 and the end of the Class Period, Eatz sold 1,204,099 shares of Immucor stock for proceeds of over $32.4 million. Of the 1,204,099 shares sold during that period, Eatz sold 874,399 shares during the Class Period, reaping proceeds of nearly $25 million, while he knew or was severely reckless in not knowing of Defendants' antitrust conspiracy and Immucor's serious quality deficiencies. Eatz decreased his holdings of Immucor stock by approximately 40% during the Class Period. Indeed, in the summer of 2007, just prior to the Company's disclosure that the FTC was investigating the Company for anticompetitive behavior, Eatz sold 350,213 shares for proceeds of more than $11 million. Furthermore, from the beginning of the third quarter of

[10] In fact, De Chirico sold the vast majority of these shares (221,871 shares) in one transaction on July 11, 2007.

fiscal 2009 to the issuance of the Notice of Intent to Revoke, Eatz sold 130,000 shares for approximately $3.4 million in proceeds.

104. Between 1998 and May 2002, Defendant Gallup only sold 2,000 shares of Immucor common stock. Then, between June 2002 and the end of the Class Period, Gallup sold 904,948 shares of Immucor common stock for proceeds of more than $23.3 million. Of the 904,948 shares Gallup sold during that period, Gallup sold 503,748 shares of Immucor common stock for proceeds of more than $13.2 million during the Class Period, while he knew or was severely reckless in not knowing of Immucor's quality issues and the Company's ongoing antitrust conspiracy.

VI. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

A. 2005 Fourth Fiscal Quarter and Year End Statements

105. On October 19, 2005, the beginning of the Class Period, Immucor filed an annual report on Form 10-K with the SEC for the fiscal year ending May 31, 2005 ("2005 10-K"). The 2005 10-K was signed by Defendant Gallup.

106. In the 2005 10-K, Defendants acknowledged that Immucor operated as a "highly regulated business" and is subject to "continuing compliance with multiple U.S. . . . statutes, regulations and standards that generally include . . . product testing [and] facilities compliance". Defendants also detailed Immucor's

relationship with the FDA, including the necessity of FDA licenses for the Company's operations and the results of a March 2005 inspection:

> An FDA facility license is issued for an indefinite period of time, subject to the FDA's right to revoke the license. As part of its overview responsibility, the FDA makes plant and facility inspections on an unannounced basis. Further, a sample of each production lot of many of the Company's products must be submitted to and approved by the FDA prior to its sale or distribution. The Company operates under U.S. Government Establishment License No. 886 granted by the FDA in December 1982 to Immucor, Inc. for the Norcross facility . . .
>
> In March 2005, the FDA inspected the Immucor, Inc. facility in Norcross, Georgia and reported two minor observations. The Company responded to the observations in May 2005. . . .
>
> In addition, each product manufactured by the Company is subject to formal product submissions and review processes by the FDA . . . Significant changes to the Company's products or facilities can require additional submission and review prior to implementation.

107. Moreover, Defendants falsely represented that Immucor's manufacturing and ongoing quality procedures were in compliance with federal regulations:

> In North America, the Company has hired and retained several employees who are highly experienced in FDA and other regulatory authority compliance, and the Company believes that its ***manufacturing and on-going quality control procedures conform to the required statutes, regulations and standards***.

108. In the 2005 10-K, Defendants also stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

109. The 2005 10-K and the statements in ¶¶106-108, were materially false and misleading because, as set forth in ¶¶38-49 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

    a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation, in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100; and

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b); and

3. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

110. In the 2005 10-K, Defendants also represented:

> In the past several years, the industry experienced ***aggressive price competition***, particularly among manufacturers that targeted large hospitals and institutions as key customers. In spite of this ***competitive environment***, the Company has maintained its worldwide sales and increased its domestic reagent market share.
>
> …
>
> The Company's overall strategy in fiscal 2005 was to continue to improve gross margin (gross profit as a percentage of sales). In this effort, the Company was successful, as gross margin increased to 60.3% for the year ended May 31, 2005 from 55.1% for the year ended May 31, 2004.
>
> …

> Reagent revenues grew to $128.8 million compared to $102.3 million in the prior year, a 25.9% increase. The growth in reagent revenues occurred as a result of traditional reagent price increases in North America, which contributed $15.9 million to the increase, and volume and price increases in proprietary Capture products.

111. The statements above were materially false and misleading because as, set forth in ¶¶75-100, Defendants failed to disclose that the Company's "aggressive" price increases, increased revenues and improved gross margins were not the result of a true "competitive environment" and instead, were the result of unsustainable, collusive pricing behavior in violation of the U.S. antitrust laws. In addition, the Company was able to report improved gross margins because, as alleged in ¶¶38-49 & 73-74, Defendants refused to expend the necessary funds to materially improve the quality function at the Company.

B. 2005 Annual Report

112. In or around October 19, 2005, Defendants issued an annual report to Immucor's shareholders (the "2005 Annual Report") which included the Company's 2005 10-K. In the letter to the shareholders that accompanied the 2005 Annual Report, Defendants De Chirico and Gallup stated that Immucor was firmly committed to four objectives, one of which was delivering a "high-quality system".

113. The 2005 Annual Report and the statements in ¶112 above were materially false and misleading because, as set forth in ¶¶38-49 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation, in violation of 21 C.F.R. §820.20;

   b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100; and

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b); and

3. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

C. 2006 First Fiscal Quarter Statements

1. 1Q Press Release and Conference Call

114. On November 10, 2005, the Company issued a press release ("1Q06 Press Release") announcing its fiscal first quarter results and 2006 guidance. In that press release, Defendant Gallup stated that the Company's growth in revenues was achieved by controlling manufacturing costs. In addition, Defendants stated:

> Revenue for the fiscal first quarter was a record $42.4 million, up 32.2% from $32.1 million in the same period last year. The $10.3 million increase in revenues was primarily the result of price increases. Gross margin improved during the quarter to 62.9% up from 57.0% in the prior year quarter.
>
> …

> Reagent gross margin grew to 71.3% during the first quarter of fiscal 2006 compared to 62.0% in the same period last year. The previously mentioned price increases and improved manufacturing efficiencies were responsible for this improvement.
>
> …
>
> The gross margin on traditional reagents was 69.2% for the current quarter, compared with 57.4% in the prior year quarter. The increase in gross margin is primarily due to price increases.

115. During the conference call with analysts on November 11, 2005 ("1Q06 Conference Call") Defendants reiterated the Company's "record" revenues. In addition, De Chirico stated the following concerning reagent gross profits:

> On the reagent side everything is going [a]s planned, efficiencies there. It is just a normal fluctuation. You will see the reagents gross profit picking up in the second quarter.

116. The statements in ¶¶114-115 above were materially false and misleading because as, set forth in ¶¶75-100, Defendants failed to disclose that the Company's "record" revenues and improved gross margins were the result of collusive pricing behavior in violation of the U.S. antitrust laws. In addition, the Company was able to report improved gross margins because, as alleged in ¶¶38-49 & 73-74, Defendants refused to expend the necessary funds to materially improve the quality function at the Company.

2. 1Q06 Form 10-Q

117. On November 10, 2005, Immucor filed its Form 10-Q with the SEC for the quarter ending August 31, 2005 ("1Q06 10-Q"). The 1Q06 10-Q was signed by Defendant Gallup.

118. In the 1Q06 10-Q, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor. In addition, Defendants stated that the decision to close Immucor's Houston facility "was driven by a number of factors including, in particular, the expense of operating two separate FDA licensed manufacturing facilities."

119. The 1Q06 Press Release, the 1Q06 Conference Call, the 1Q06 10-Q and the statements in ¶118 above were materially false and misleading because, as set forth in ¶¶38-49 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation, in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100; and

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b); and

3. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

120. In the 1Q06 10-Q, Defendants reiterated the Company's positive financial results identified above in ¶114 and further represented that the "improvement in gross margin" for this quarter was due in large part to reagent price increases "attributable in part to the cancellation of supply agreements with two group purchasing organizations in January 2005 in order to increase member purchasing prices". The 1Q06 10-Q further represented:

> Reagent revenues grew to $39.2 million compared to $28.5 million in the prior year quarter, a 37.6% increase. The growth in reagent revenue occurred primarily as a result of traditional reagent price increases in North America, which contributed $9.0 million to the increase.

121. The statements above were materially false and misleading because Defendants failed to disclose that the Company's positive financial results as well as the price increases were the result of collusive, anticompetitive behavior in violation of the U.S. antitrust laws. In addition, the Company was able to report improved gross margins because, as alleged in ¶¶38-49 & 73-74, Defendants refused to expend the necessary funds to materially improve the quality function at the Company.

D. 2006 Second Fiscal Quarter Statements

1. 2Q06 Press Release and Conference Call

122. On January 5, 2006, the Company issued a press release announcing its fiscal second quarter results (the "2Q06 Press Release"). In that press release, Defendant De Chirico stated that the Company's successful results were achieved by lowering costs. Furthermore, Defendants stated:

> Revenues for the fiscal second quarter were a record $44.0 million, up 34.9% from $32.6 million in the same period last year. The $11.4 million increase was primarily the result of price increases.
>
> …
>
> Reagent gross margin grew to 70.9% during the second quarter of fiscal 2006 compared to 61.4% in the same period last year. The previously mentioned price increases and improved manufacturing efficiencies were responsible for this improvement.

123. On January 6, 2006, in a conference call ("2Q06 Conference Call") with analysts in which Gallup and De Chirico participated, Defendants reiterated that they were very pleased with the Company's record revenues and stated the following concerning price increases:

> ***Analyst***
> …just thinking about the pricing component this quarter, the press release referred to the majority of the year-over-year increase being related to pricing. Can you drill that down a little bit more for us?
>
> …

> ***Edward Gallup***
> [T]his 10.4 came from price increase, so there is an additional $1 million from volume, plus the number – the 0.5 million Nino just mentioned. So about 1.5 million from volume growth.

124. Analysts were focused on Immucor's price increases and viewed them as a positive factor affecting the Company's business. For example, a March 14, 2006 RBC Capital Markets report, stated that the price increases on traditional reagents was a "positive development for Immucor".

125. The statements in ¶¶122-123 above were materially false and misleading because as, set forth in ¶¶75-100, Defendants failed to disclose that the Company's "record" results and its price increases were the result of collusive pricing behavior in violation of the U.S. antitrust laws. In addition, the Company was able to report improved gross margins and lower costs because, as alleged in ¶¶38-49 & 73-74, Defendants refused to expend the necessary funds to materially improve the quality function at the Company.

2. 2Q06 Form 10-Q

126. On January 6, 2006, Immucor filed its Form 10-Q with the SEC for the quarter ending November 30, 2005 ("2Q06 10-Q"). The 2Q06 10-Q was signed by Defendant Gallup.

127. In the 2Q06 10-Q, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed

in statements made by Immucor. In addition, Defendants stated that the decision to close Immucor's Houston facility "was driven by a number of factors including, in particular, the expense of operating two separate FDA licensed manufacturing facilities."

128. The 2Q06 Press Release, the 2Q06 Conference Call, the 2Q06 10-Q and the statements in ¶127 above were materially false and misleading because, as set forth in ¶¶38-49 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

    a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation, in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100; and

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b); and

3. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

129. In the 2Q06 10-Q, Defendants set forth the financial results described in paragraph ¶122 above and further represented the "improvement in revenues and gross margins" for this quarter was due primarily to reagent price increases which was attributed in part to the cancellation of the agreements with group purchasing organizations "in order to increase member purchasing prices". In addition, Defendants stated:

> Reagent revenues grew to $40.0 million compared to $28.2 million in the prior year quarter, a 41.8% increase. The growth in traditional reagent revenue (i.e. products not utilizing the Company's patented Capture® technology) occurred mainly as a result of price increases.
>
> …
>
> Overall gross margin improved during the quarter to a record 64.8%, up from 56.1% in the prior year quarter. Gross margin on traditional reagents for the quarter ended November 30, 2005 increased to 68.4% for the current quarter from 56.7% for the prior year quarter as a result of the price increases discussed above as well as from improved manufacturing efficiencies.

130. The statements above were materially false and misleading because as, set forth in ¶¶75-100, Defendants failed to disclose that the Company's "improvement in revenues", cancellation of GPO contracts and increased prices were achieved as part of a collusive anticompetitive campaign in violation of U.S. antitrust laws. In addition, the Company was able to report improved gross margins and "improved manufacturing efficiencies" because, as alleged in ¶¶38-49 & 73-74, Defendants refused to expend the necessary funds to materially improve the quality function at the Company.

E. March 2006 FDA Inspection Identifies Numerous Violations

131. Between March 7 through 16, 2006, the FDA inspected Immucor's Norcross facility and found thirteen types of violations of FDA regulations. The violations that the FDA found included, *inter alia*, failure to "always submit Medical Device Reports as required," failure to report "changes to an approved

biologics license application," failure to investigate "process deviations and non-conforming product" (*i.e.*, root cause failures), and "validation/qualification studies of processes, equipment and test methods were not always complete." For each violation, the FDA noted a number of different incidents of the Company's failure to adhere to proper quality procedures and policies.

132. For example, with respect to the Company's failure to submit MDRs, a violation of 21 C.F.R. §803.50(a)(2), the FDA found that the Company had received numerous customer complaints about Immucor's products beginning at least as early as June 2005, including product malfunctions. Despite having received such reports, the FDA noted multiple incidents whereby the Company failed to report these occurrences to the FDA.

133. In addition, the FDA identified multiple separate incidents of violations of 21 C.F.R. §820.100, the federal regulation that pertains to root cause failures. These violations dated back to as early as March 2005 and continued through February 2006.

134. At the conclusion of the March 2006 FDA inspection, the FDA provided management with a Form 483 detailing the various violations the FDA had identified. Defendant Eatz, along with CW1 were present at the meeting with FDA personnel during which time the inspection results were discussed. Despite

the seriousness of these violations, Defendants failed to disclose the material fact that the Company's quality function was deficient and that Immucor was not in material compliance with FDA regulations and was not taking the necessary steps to be in compliance.

F. 2006 Third Fiscal Quarter Statements

1. 3Q06 Press Release and Conference Call

135. On April 5, 2006, the Company issued a press release announcing its fiscal third quarter results (the "3Q06 Press Release"). In that press release, Defendant Gallup stated that he was extremely pleased with the Company's "all-time highs" achieved in revenues and gross margin. Furthermore, the Company stated:

> Revenues for the fiscal third quarter were a record $47.1 million, up 24% from $38.0 million in the same period last year. The $9.1 million increase was primarily the result of price increases. Gross margin improved during the quarter to a record 68.2% up from 63.1% in the prior year quarter.
>
> …
>
> Reagent gross margin grew to 74.0% during the third quarter of fiscal 2006 compared to 69.7% in the same period last year. The previously mentioned price increases and improved manufacturing efficiencies were responsible for this improvement.
>
> …
>
> The gross margin on traditional reagents was 71.7% for the current quarter, compared with 65.6% in the prior year quarter. The increase in gross margin is primarily due to price increases in the United States

136. On April 6, 2006, in a conference call with analysts (the "3Q06 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendant Gallup reiterated the Company's positive financial results and stated that they were the result of the Company's "business model . . . working extremely well." In addition, Defendant De Chirico stated that the Company's gross profit would continue to improve as a result of the Company's cost control.

137. The statements above in ¶¶135-136 were materially false and misleading because as, set forth in ¶¶75-100, Defendants failed to disclose that the Company's "all-time highs" in revenues, improved gross margins and its price increases were the result of collusive pricing behavior in violation of the U.S. antitrust laws. In addition, the Company was able to report improved gross margins and manufacturing efficiencies through "cost control" because, as alleged in ¶¶38-53 & 73-74, Defendants refused to expend the necessary funds to materially improve the quality function at the Company.

2. 3Q06 10-Q

138. On April 6, 2006, Immucor filed its Form 10-Q with the SEC for the quarter ending February 28, 2006 ("3Q06 10-Q"). The 3Q06 10-Q was signed by Defendant Gallup.

139. In the 3Q06 10-Q, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor. In addition, Defendants stated that the decision to close Immucor's Houston facility "was driven by a number of factors including, in particular, the expense of operating two separate FDA licensed manufacturing facilities."

140. The 3Q06 Press Release, the 3Q06 Conference Call, the 3Q06 10-Q and the statements in ¶139 above were materially false and misleading because, as set forth in ¶¶38-53 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

    a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured

compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

141. In the 3Q06 10-Q, Defendants set forth the financial results described in ¶135 above and further represented the "improvement in revenues and gross margins" for this quarter was due primarily to reagent price increases which was attributed in part to the cancellation of the agreements with group purchasing organizations "in order to increase member purchasing prices". Defendants also represented:

> Traditional reagent revenues grew to $34.0 million compared to $25.8 million in the prior year quarter, a 32% increase. The growth in traditional reagent revenue (i.e. products not utilizing the Company's patented Capture® technology) occurred mainly as a result of price increases. . .
>
> …

> Overall gross margin improved during the quarter ended February 28, 2006 to a record 68%, up from 63% in the prior year quarter. Gross margin on traditional reagents for the quarter ended February 28, 2006 increased to 72% for the current quarter from 66% for the prior year quarter as a result of the price increases discussed above as well as from manufacturing efficiencies.

142. The statements in ¶141 above were materially false and misleading because Defendants failed to disclose that the Company's positive financial results were achieved as a result of collusive anticompetitive behavior in violation of the U.S. antitrust laws. In addition, Defendants failed to disclose that Immucor's improved gross margins and ability to achieve "manufacturing efficiencies" were achieved in material part while the Company did not spend needed funds on the quality function at its Norcross facility, as detailed above in ¶¶38-53 & 73-74.

G. Fiscal 2007 Guidance Call with Investors

143. On May 23, 2006, in a conference call with investors (the "07 Guidance Call"), in which Gallup and De Chirico participated, Gallup reiterated that the Company's "business model [was] working extremely well." In addition, when asked about Immucor's price increases of blood reagents, Defendants represented:

> ***Edward Gallup***
> . . . as you know, we implemented a 10% increase last January and of course that rolls out during the year and as you said we have a couple of large accounts that are renewing as we speak or next month and we do intend to have a 10% increase again next January. . .
>
> ***Analyst***
> In terms of taking another 10% price increase this coming January, does that get you to the same level as J&J or would that actually move you north of their pricing?
>
> ***Dr. Nino De Chirico***
> We don't know what J&J is going to do, but we will be very close.
>
> ***Edward Gallup***
> If they do what we -- it is hard as you well understand, it's a little bit hard with the broad product mix that we both have, but we think that we -- we know where we were at the 10% and we think maybe on a blended rate they were at about 5, so next year we should be very, very close to them. And in the future we should certainly pass them because we are the leader in the market and we do deliver more value.

144. The 07 Guidance Call and the statements in the paragraph above were materially false and misleading because Defendants failed to disclose that the Company's financial results and price increases were achieved as part of the Company's collusive, anticompetitive campaign in violation of the U.S. antitrust laws. In addition, contrary to De Chirico's statement, Immucor did know what "J&J [was] going to do" with respect to price increases since Immucor and Ortho were colluding to raise prices of blood reagents in violation of the antitrust laws.

H. 2006 Fiscal Fourth Quarter and Year End Results

1. 4Q06 and Year End 2006 Press Release and Conference Call

145. On July 26, 2006, the Company issued a press release announcing its fiscal fourth quarter and year end results (the "4Q06 Press Release"). Defendant Gallup stated that "all-time highs" were achieved in revenues, gross margin and net income. Defendant De Chirico also touted the Company's "strategies to grow [its] business." In that press release, the Company further stated:

> Revenue for the fiscal fourth quarter was a record $50.0 million, up 19% from $42.1 million in the same period last year. Of the $7.9 million total increase in revenues, approximately $6.0 million came from price increases.
>
> …
>
> Reagent gross margin grew to 77.5% during the fourth quarter of fiscal 2006 compared to 73.0% in the same period last year. The previously mentioned price increases and improved manufacturing efficiencies were responsible for this improvement.
>
> …
>
> The gross margin on traditional reagents was 76.6% for the current quarter, compared with 70.8% in the prior year quarter. The increase in gross margin is primarily due to price increases in the United States.

146. During the conference call with analysts on July 27, 2006 (the "4Q06 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendants reiterated the Company's strong financial results and stated that Immucor's "business model continues working extremely well." In addition,

Defendants stated that the Company's gross margins were driven by price increases and that these margins were sustainable.

147. The statements in ¶¶145-146 above were materially false and misleading because Defendants failed to disclose that the Company's positive financial results were not sustainable because they were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws as detailed above in ¶¶75-100. Defendants also did not disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function, as detailed above in ¶¶38-53 & 73-74.

2. 2006 10-K

148. On August 1, 2006, Immucor filed its annual report on Form 10-K with the SEC for the fiscal year ending May 31, 2006 ("2006 10-K"). The 2006 10-K included the financial results identified above in ¶145 and were materially false and misleading for the reasons identified above in ¶147. The 2006 10-K was signed by Defendants De Chirico, Eatz, and Gallup.

149. In the 2006 10-K, Defendants noted that Immucor was a "highly regulated business" and subject to "continuing compliance with multiple U.S. . . . statutes, regulations and standards that generally include . . . product testing [and] facilities compliance". Defendants also stated:

> An FDA facility license is issued for an indefinite period of time, subject to the FDA's right to revoke the license. As part of its overview responsibility, the FDA makes plant and facility inspections on an unannounced basis. Further, a sample of each production lot of many of the Company's products must be submitted to and cleared by the FDA prior to its sale or distribution. The Company operates under U.S. Government Establishment License No. 886 granted by the FDA in December 1982 to Immucor, Inc. for the Norcross facility . . .
>
> In March 2006, the FDA inspected the Immucor, Inc. facility in Norcross, Georgia and reported 13 observations. The Company responded to the observations in April 2006, outlining its plans to implement corrective actions as appropriate. . . The FDA routinely verifies company implementations and commitments during subsequent visits.
>
> …
>
> Our instruments, reagents and other products are subject to regulation by governmental and private agencies in the United States and abroad, which regulate the testing, manufacturing, packaging, labeling, distribution and marketing of medical supplies and devices. . . Also, the FDA and international agencies have the authority to require a recall or modification of products in the event of a defect.
>
> The FDA and other agency clearances generally are required before we can market new instruments or reagents in the United States or make significant changes to existing products.

150. Moreover, Defendants falsely represented that Immucor's manufacturing and ongoing quality procedures were in compliance with federal regulations:

> In North America, the Company has hired and retained several employees who are highly experienced in FDA and other regulatory authority compliance, and the Company believes that ***its manufacturing and on-going quality control procedures conform to the required statutes, regulations and standards***.

151. In the 2006 10-K, Defendants claimed that the Company "experienced a low staff turnover rate in fiscal 2006." In addition, Defendants included the following risk factor:

> ***We are highly dependent on our senior management team and other key employees, and the loss of one or more of these employees could adversely affect our operations.***
>
> Our success is dependent upon the efforts of our senior management and staff, including sales, technical and management personnel, many of whom have very specialized industry and technical expertise that is not easily replaced. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited. Our future success depends on our ability to continue to attract, retain and motivate qualified personnel. There is intense competition for medical technologists and in some markets there is a shortage of qualified personnel in our industry. If we are unable to continue to attract or retain highly qualified personnel, the development, growth and future success of our business could be adversely affected.

152. The 4Q06 Press Release, the 4Q06 Conference Call, the 2006 10-K and the statements in ¶¶149-151, were materially false and misleading because, as set forth in ¶¶38-54 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

153. In addition, the statements in ¶151 above were materially false and misleading because as set forth in ¶¶43-44, there was a high-turnover rate in Immucor's quality department and significant reductions in headcount of quality positions.

154. In its 2006 10-K, Defendants reiterated the Company's strong financial results discussed above in ¶145. Defendants also claimed that Immucor was "well positioned to compete favorably in the blood bank business principally because of the completeness of its product line, quality and ***competitive pricing structure*** for its products."

155. The statements in ¶154 above were materially false and misleading because Defendants failed to disclose that Immucor was not engaging in true competition nor was it "well positioned to compete in the blood bank business" because of a "competitive pricing structure" of its products. Instead, Immucor was engaged in an anticompetitive pricing campaign along with its main competitor, Ortho in violation of U.S. antitrust laws, as discussed above in ¶¶75-100. In addition, Defendants also did not disclose that the Company's financial results were achieved in material part by Defendants' decision not to spend needed funds on critical quality function, as detailed above in ¶¶38-54 & 73-74.

I. 2006 Annual Report

156. In or around August 1, 2006, Defendants provided an annual report to Immucor's shareholders ("2006 Annual Report") which included the Company's 2006 10-K. In the letter to the shareholders that accompanied the 2006 Annual

Report, Defendants De Chirico and Gallup stated that Immucor had a "relentless commitment" to among other things, delivering "a high-quality system."

157. The 2006 Annual report and the statements identified in ¶156 above were materially false and misleading because, as set forth in ¶¶38-54 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. 803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the

Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

J. 2007 First Fiscal Quarter Statements

1. 1Q07 Press Release and Conference Call

158. On October 4, 2006, the Company issued a press release announcing its fiscal first quarter results (the "1Q07 Press Release"). In that press release, Defendant Gallup stated "all-time highs were achieved in revenues and net income for the quarter." Defendant De Chirico further stated that the Company's strategies to grow the business "continue to generate outstanding results both in terms of revenues and net income." The Company further stated:

> Revenue for the fiscal first quarter was a record $51.0 million, up 20% from $42.4 million in the same period last year. Of the $8.6 million total increase in revenues, approximately $4.4 million came from price increases in the United States . . . Gross margin improved during the quarter to 67.7% up from 62.9% in the prior year quarter.
>
> …

> The gross margin on traditional reagents was 74.2% for the current quarter, compared with 69.2% in the prior year quarter. The increase in gross margin is primarily due to price increases in the United States.

159. On October 5, 2006 in a conference call with analysts ("1Q07 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendant Gallup stated that the Company's "business model continues working extremely well."

160. The statements above in ¶¶158-159 were materially false and misleading because Defendants failed to disclose that the Company's business model achieved such positive financial results through collusive anticompetitive behavior in violation of the U.S. antitrust laws. In addition, Defendants failed to disclose that Immucor's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-54 & 73-74.

161. In addition, during the conference call, Defendant De Chirico discussed a new Immucor product called "whole blood control". With respect to this new product, De Chirico stated:

> We have a couple of new reagents that we -- important reagents, that we have developed just for the ECHO. One of which is the quality control reagent, that we call [whole] blood control. This is in some way a breakthrough in the industry, because we are going to use a real -- mimic real blood to do quality control.

> It is a breakthrough [product] because in the past and the competitors, they do not use or we did not use real blood. We used reagents. That is not real quality control. Because when you test the instrument with real blood, the instrument can perform in a different way. Then this is one of the new reagents, the [whole] blood quality control, that we are going also to use in other instruments in the future.

162. The 1Q07 Press Release, the 1Q07 Conference Call and the statements in ¶161 above was materially false because, as set forth in ¶¶38-55 Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDR's to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the

Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

2. 1Q07 Form 10-Q

163. On October 5, 2006, Immucor filed a Form 10-Q with the SEC for the period ending August 31, 2006 ("1Q07 10-Q"). The 1Q07 10-Q was signed by Defendant De Chirico.

164. In the 1Q07 10-Q, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

165. The 1Q07 10-Q and the statements in ¶164above were materially false and misleading because, as set forth in ¶¶38-55 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

   b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

   c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses

which were essential for it to continue to function as a profitable and viable company.

166. The 1Q07 10-Q included the positive financial results that were discussed on the 1Q07 press release. In addition, the 1Q07 10-Q reiterated that the improvement in revenues and gross margins were due in large part to reagent price increases. Furthermore, the 1Q07 10-Q provided that the "growth in traditional reagent revenue . . . occurred mainly as a result of price increases."

167. The statements in ¶166 above were materially false and misleading because Defendants failed to disclose that as detailed above at ¶¶75-100 the Company's improvements in revenues and price increases were the result of a collusive, anticompetitive campaign along with Immucor's main competitor in violation of the U.S. antitrust laws. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55 & 73-74.

K. 2007 Second Fiscal Quarter Statements

1. 2Q07 Press Release and Conference Call

168. On January 3, 2007, the Company issued a press release announcing its fiscal second quarter results (the "2Q07 Press Release"). In that press release,

Defendant De Chirico touted the Company's "all-time highs" achieved in revenues and net income. Defendants also stated:

> Revenue for the fiscal second quarter was a record $54.4 million, up 24% from $44.0 million in the same period last year. Of the $10.4 million total increase in revenues . . . approximately $5.3 million came from price increases in the United States.
>
> …
>
> The gross margin on traditional reagents was 74.9% for the current quarter, compared with 68.4% in the prior year quarter. The increase in gross margin is primarily due to price increases in the United States.

169. In a conference call with analysts the next day ("2Q07 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendant Gallup reiterated the Company's strong financial results and that "[t]hese record results speak very well for the overall strengths of our business." In addition, with respect to price increases, Defendants stated:

> ***Analyst***
> Then had you had any of the contracts since your major price increases a couple years ago, the big 50% jump, any of those contracts that have come up for subsequent renewal or for new pricing? If so, can you give us a sense of what the average price increase you are seeing?
>
> ***De Chirico***
> Most of these contracts, as you may remember, the Premier, Novation. The contracts that are up for renewal, we will see some like Consorta that were kept. HealthTrust we kept. These are coming up, HealthTrust is coming up for renewal in the first quarter of 2007 this year. This is more or less the dynamic of the pricing. Of course, we

> will try to get an additional price increase; of course, much less than the one we had two years ago.

170. The statements in ¶¶168-169 above were materially false and misleading because Defendants failed to disclose that Immucor's financial results, including, the "all-time highs" in revenues as well as the price increases were achieved as a result of the Company's collusive anticompetitive pricing behavior in violation of U.S. antitrust laws. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55 & 73-74.

2. 2Q07 10-Q

171. On January 5, 2007, Immucor filed a Form 10-Q with the SEC for the period ending November 30, 2006 ("2Q07 10-Q"). The 2Q07 10-Q was signed by Defendant De Chirico.

172. In the 2Q07 10-Q, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

173. The 2Q07 Press Release, the 2Q07 Conference Call, the 2Q07 10-Q and the statements in ¶172 above were materially false and misleading because, as set forth in ¶¶38-55 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

   b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

   c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses

which were essential for it to continue to function as a profitable and viable company.

174. The 2Q07 10-Q also included the positive financial results that were discussed above in ¶168 and reiterated that the improvement in revenues and gross margins were due in large part to reagent price increases. In addition, the 2Q07 10-Q provided that the "growth in traditional reagent revenue . . . occurred mainly as a result of price increases." The 2Q07 10-Q also stated:

> The growth in traditional reagent revenue occurred mainly as a result of price increases in the U.S. Traditional reagent sales have historically been our primary source of revenue and still constitute a very significant portion of our business.

175. The above statements were materially false and misleading because Defendants failed to disclose that the Company's positive financial results were achieved through collusive, anticompetitive behavior in violation of the U.S. antitrust laws as detailed above in ¶¶75-100. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55 & 73-74.

L. 2007 Third Fiscal Quarter Statements

1. 3Q07 Press Release and Conference Call

176. On April 4, 2007, the Company issued a press release announcing its fiscal third quarter results (the "3Q07 Press Release"). Defendant De Chirico stated that the Company was extremely pleased with the "all-time highs" achieved in revenues and net income for the quarter. In that press release, Defendants further stated:

> Revenue for the fiscal third quarter was a record $57.1 million, up 21% from $47.1 million in the same period last year. Of the $10.0 million total increase in revenues, approximately $0.6 million came from volume increases including instrument, warranty and service revenue in the United States, approximately $8.2 million came from price increases in the United States.
>
> …
>
> Reagent gross margin grew to 77.6% during the third quarter of fiscal 2007 compared to 74.0% in the same period last year. Price increases were primarily responsible for this improvement.

177. In a conference call with analysts the next day ("3Q07 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendants reiterated the Company's strong financial results which reflected "the overall strength of [Immucor's] business." In addition, with respect to price increases, De Chirico stated:

> Well, price increases are very complex price differentiation strategy like we call. It's a very different -- a very complex process. The price increase you see in this quarter benefits from a price increase we gave

> to two groups at the end of last year, and these two groups at price is not changed since 2002. Then it's a very complex process. We believe that this fiscal year we will end up with around $25 million in price increase. But, of course, we do not expect the same level of price increase in the next fiscal year and going forward.

178. The statements above in ¶¶176-177 were materially false and misleading because they provided the false impression that Defendants were operating in a competitive business. In fact, Defendants failed to disclose that the Company's positive financial results and its decision to raise prices at Immucor were not the result of a "very complex price differentiation strategy" but instead was the result of collusive, anticompetitive pricing behavior in violation of U.S. antitrust laws as detailed above in ¶¶75-100. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55 & 73-74.

2. 3Q07 10-Q

179. On April 5, 2007, Immucor filed a Form 10-Q with the SEC for the period ending February 28, 2007 ("3Q07 10-Q"). The 3Q07 10-Q was signed by Defendant De Chirico.

180. In the 3Q07 10-Q, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

181. The 3Q07 Press Release, the 3Q07 Conference Call, the 3Q07 10-Q and the statements in ¶180 above were materially false and misleading because, as set forth in ¶¶38-55 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

    a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 CFR 820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the

Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

182. The 3Q07 10-Q also included the positive financial results provided above in ¶176 and reiterated that the improvement in revenues and gross margins were due in large part to reagent price increases. In addition, the 3Q07 10-Q stated that the "growth in traditional reagent revenue . . . occurred mainly as a result of price increases." In addition, the 3Q07 10-Q provided that gross margin on the Company's traditional reagents for the quarter increased to 76% "primarily as a result of the price increases."

183. The statements in ¶182 above were materially false and misleading because Defendants failed to disclose that the Company's price increases and overall positive financial results were achieved through collusive, anticompetitive behavior in violation of the U.S. antitrust laws as detailed above in ¶¶75-100. In

addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55 & 73-74.

184. In fact, shortly after announcing its fiscal third quarter results, in a form 8-K filed with the SEC on April 30, 2007, the Company announced that it had amended the Company's code of conduct. Among other changes, the Company's code of conduct included a provision entitled "Antitrust and Competition Laws" which stated that "the Company and its employees are expected to comply with both the letter and the spirit of U.S. and non-U.S. laws relating to antitrust and unfair trade practices." In the Company's Form 8-K however, Defendants failed to disclose that the Company and its employees had been operating in violation of the federal antitrust laws during the Class Period.

M. 2007 Fiscal Fourth Quarter and Year End Results

1. 4Q07 and Year End Press Release and Conference Call

185. Shortly before issuing the Company's 2007 fiscal fourth quarter and year end results, on July 11, 2007 and a few months before the Company disclosed the subpoena issued by the FTC in October 2007, Defendant De Chirico sold a substantial portion of his Immucor stock. De Chirico's sale of Immucor stock on

July 11 allowed him to reap proceeds of nearly $6 million and these sales represented 42% of his holdings at the time. Defendant Eatz also sold a substantial number of his shares during the around this time frame. Indeed, between June and August 2007, Eatz sold 350,213 shares for proceeds of more than $11 million.

186. On July 25, 2007, the Company issued a press release announcing its fiscal fourth quarter and year end results (the "4Q07 Press Release"). In that press release, De Chirico stated the Company had achieved "all-time highs" in revenues and gross margin. Defendants further stated:

> Revenue for the fiscal fourth quarter was a record $61.1 million, up 22% from $50.0 million in the same period last year. Of the $11.1 million total increase in revenues, approximately $2.0 million came from volume increases including instrument, warranty and service revenue in the United States, approximately $7.6 million came from price increases in the United States.
>
> …
>
> Reagent gross margin grew to 80.7% during the fourth quarter of fiscal 2007 compared to 77.5% in the same period last year. The previously mentioned price increases were responsible for this improvement.
>
> …
>
> The gross margin on traditional reagents was 79.5% for the current quarter, compared with 76.6% in the prior year quarter. . . The increase in gross margin is primarily due to price increases in the United States.

187. In a conference call on July 26, 2007 ("4Q07 Conference Call"), in which Gallup and De Chirico participated, Defendants reiterated the Company's strong financial results.

188. The statements above in ¶¶186-187 were materially false and misleading because Defendants failed to disclose that the Company's positive financial results were achieved through collusive, anticompetitive behavior in violation of the U.S. antitrust laws as detailed above in ¶¶75-100. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55 & 73-74.

2. 2007 10-K

189. On July 27, 2007, the Company filed its annual report on Form 10-K with the SEC for the period ending May 31, 2007 ("2007 10-K"). The 2007 10-K was signed by Defendants De Chirico and Eatz.

190. The 2007 10-K represented that Immucor was a "highly regulated" business "subject to continuing compliance with multiple U.S. . . . statutes, regulations and standards that generally include . . . product testing [and] facilities compliance." In addition, Defendants stated:

> In the U.S., an FDA facility license is issued for an indefinite period of time, subject to the FDA's right to revoke the license. As part of its overview responsibility, the FDA makes plant and facility inspections on an unannounced basis. Further, a sample of each production lot of many of our products must be submitted to and cleared by the FDA prior to their sale or distribution. In 2006, we consolidated the Gamma Biologicals, Inc., Houston facility (U.S. Government Establishment License No. 435) under the Immucor, Inc. License No. 886, and the Houston facility now operates under the Immucor, Inc. name.
>
> In addition, each product manufactured by us is subject to formal product submissions and review processes by the FDA and other regulatory bodies.

191. Moreover, Defendants falsely represented that Immucor's manufacturing and ongoing quality procedures were in compliance with federal regulations:

> In North America, we have hired and retained several employees who are highly experienced in FDA and other regulatory authority compliance, and we believe that our ***manufacturing and on-going quality control procedures conform to the required statutes, regulations and standards***.

192. In the 2007 10-K, Defendants claimed that Immucor had "experienced a low staff turnover rate in fiscal 2007" and included the following risk factor:

> ***We are highly dependent on our senior management team and other key employees, and the loss of one or more of these employees could adversely affect our operations.***
>
> Our success is dependent upon the efforts of our senior management and staff, including sales, technical and management personnel, many of whom have very specialized industry and technical expertise that is not easily replaced. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited.

> Our future success depends on our ability to continue to attract, retain and motivate qualified personnel. There is intense competition for medical technologists and in some markets there is a shortage of qualified personnel in our industry. If we are unable to continue to attract or retain highly qualified personnel, the development, growth and future success of our business could be adversely affected.

193. The 4Q07 Press Release, the 4Q07 Conference Call, the 2007 10-K and the statements above in ¶¶190-192, were materially false and misleading because, as set forth in ¶¶38-55 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

    a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the

Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

194. In addition, the statements in ¶192 above were materially false and misleading because as set forth in ¶¶43-44, there was a high-turnover rate in Immucor's quality department and significant reductions in headcount of quality positions.

195. In the 2007 10-K, Defendants further represented that Immucor's "industry and markets we operate in are highly competitive" and that the Company was "well positioned to compete favorably in the blood bank business principally because of the completeness of our product line, reliability and quality of our products, [and] competitive pricing structure."

196. The 2007 10-K included the financial results identified above in ¶186 and stated the following concerning price increases:

> Our overall gross margin increased to 71% for fiscal year 2007 from 66% achieved in fiscal year 2006 and 60% achieved in fiscal 2005. The 22% increase in revenue and a 6% improvement in overall gross margin during the year ended May 31, 2007, as compared to the prior year period, were mainly attributable to the price increases introduced in fiscal 2006 and 2007.
>
> …
>
> The 20% growth in traditional reagent revenue (i.e. products not using our patented Capture technology) in fiscal 2007 compared to fiscal 2006 occurred mainly as a result of price increases in the United States. Traditional reagent sales have historically been our primary source of revenue and still constitute roughly 70% of our revenue.
>
> …
>
> The 34% growth in traditional reagent revenue (i.e. products not using our patented Capture technology) occurred mainly as a result of price increases.

197. The statements in ¶196 above were materially false and misleading because Defendants failed to disclose that the Company's improved revenues and its price increases were achieved through collusive, anticompetitive means in violation of U.S. antitrust laws as discussed above in ¶¶75-100. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55, 73-74.

N. 2007 Annual Report

198. In or around July 27, 2007, the Company provided its 2007 annual report to Immucor shareholders ("2007 Annual Report"). The 2007 10-K was included in the 2007 Annual Report as well as a letter to shareholders from Defendant De Chirico. In that letter, Defendant De Chirico attributed the Company's "outstanding" financial performance to one of the Company's main objectives, namely to "deliver high quality." In addition, the letter stated that the Company had "significant advances in quality during the year . . . with a new Quality Policy that improves everything from the way we serve our customers to the way we handle operations."

199. The 2007 Annual Report and the statements in ¶198 above were materially false and misleading because, as set forth in ¶¶38-55 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;
2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 CFR §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

O. 2008 Fiscal First Quarter Statements

1. 1Q08 Press Release and Conference Call

200. On October 3, 2007, Immucor announced its fiscal first quarter results (the "1Q08 Press Release"). Defendant De Chirico stated that the Company

achieved "record" quarterly revenues and net income. In addition, De Chirico stated that the Company's "strategies to grow [its] business and the execution of [Immucor's] plan continue to generate outstanding results." The press release further stated:

> Revenue for the fiscal first quarter was a record $63.6 million, up 25% from $51.0 million in the same period last year. Of the $12.6 million total increase in revenues, approximately $1.5 million came from volume increases including instrument, warranty and service revenue in the United States, approximately $8.7 million came from price increases in the United States,
>
> …
>
> The gross margin on traditional reagents was 79.6% for the current quarter, compared with 74.2% in the prior year quarter. The increase in gross margin is primarily due to price increases in the United States.

201. On October 4, 2007, in a conference call with analysts ("1Q08 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendants reiterated the Company's strong financial performance, including its "record" revenues which according to defendant Gallup "speaks very well for the overall strengths of [Immucor's] business." In addition, Defendants stated the following:

> ***Analyst***
> And lastly if you can comment on the competitive landscape, especially for the midsized labs considering your Echo launch, have you seen anything different with your launch?

> ***Dr. Nino De Chirico***
> In the medium and small customers, our competitors remain Johnson & Johnson, Ortho-Clinical Diagnostics, [Progill] and we are competing.
>
> …
>
> ***Analyst***
> Can you just go over your price increase strategy? I know you've been implementing about 10% every year. Now, do you guys implement price increases on all your customers all at once or does it go in stages? And if yes, do we have more coming in future quarters?
>
> ***Dr. Nino De Chirico***
> The answer to the first question is yes. There is a price differentiation strategy that we talk in our K -- in our 10-K and we talked in our conference. There is different buckets, depends on our customer loyalty to Immucor products. In terms of future, as we speak, we are looking at what the strategy is going to be and the final decision is going to be taken in the next few weeks.

202. The statements in ¶¶200-201 above were materially false and misleading because Defendants failed to disclose that the Company's "record" financial results were achieved through collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws as discussed above in ¶¶75-100. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material part while the Company did not spend needed funds on critical quality function at its Norcross facility, as detailed above in ¶¶38-55 & 73-74.

2. 1Q08 10-Q

203. On October 5, 2007, Immucor filed with the SEC a Form 10-Q for the period ending August 31, 2007 ("1Q08 10-Q"). The 1Q08 10-Q was signed by Defendant De Chirico.

204. In the 1Q08 10-Q, Defendants represented that as part of the immunohematology industry, Immucor was regulated by the FDA. In addition, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

205. The 1Q08 Press Release, the 1Q08 Conference Call, the 1Q08 10-Q and the statements in ¶204 above were materially false and misleading because, as set forth in ¶¶38-55 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important

to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDR's to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or

procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

206. Indeed, around this time, Defendants knew or were severely reckless in disregarding that the Company had committed a serious FDA violation as detailed above in ¶¶60-61. After Tama Copeland, the Director of Red Blood Cell Manufacturing had circumvented the Company's standard operating procedures and FDA regulation for investigative reports, Defendants did not properly investigate or remedy the matter and removed CW1, the Vice President of Quality, from the investigation.

207. The 1Q08 10-Q included the financial results identified above in ¶200 and also stated the following concerning price increases of blood reagents:

> The 20% growth in traditional reagent revenue in the 2008 Quarter compared to the 2007 Quarter occurred mainly as a result of price increases in the United States. Traditional reagent sales have historically been our primary source of revenue and still constitute roughly 70% of our revenues.
>
> …
>
> Overall gross margin improved during the 2008 Quarter to 72%, up from 68% in the 2007 Quarter, due to improvement in margins in all three main categories of our business. Gross margin on traditional reagents improved by 6% in the 2008 Quarter as compared to the 2007 Quarter primarily due to price increases.

208. The statements in ¶207 above were materially false and misleading because Defendants failed to disclose that as detailed above at ¶¶75-100 the Company's positive financial results as well as the price increases were achieved through collusive, anticompetitive means in violation of U.S. antitrust laws. In addition, as stated above in ¶¶38-55 & 73-74, Defendants failed to disclose that the Company's improved gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function.

P. 2008 Fiscal Second Quarter Statements

1. 2Q08 Press Release and Conference Call

209. On January 7, 2008, Immucor announced its fiscal second quarter results (the "2Q08 Press Release"). In the press release, Defendant De Chirico stated that the Company was pleased with the Company's quarterly results. Furthermore, the Company stated:

> Revenue for the fiscal second quarter was $61.9 million, up 14% from $54.4 million in the same period last year. Of the $7.5 million total increase in revenues, approximately $6.6 million came from price increases in the United States. . .

210. On January 8, 2008, in a conference call with analysts ("2Q08 Conference Call"), in which Gallup, and De Chirico participated, Defendants reiterated the Company's positive financial results and stated the following concerning price increases:

> ***Analyst***
> When you are increasing your reagent pricing, are you still doing so just below where Johnson & Johnson is doing it?
>
> ***Nino De Chirico***
> In general, this is true. We don't know what they are doing -- you know, they have a benefit that they can listen to this conference call, and we don't have the conference call from them. But we don't know what they are doing now, honestly. Like what you said is exactly true. Our prices are in general lower than theirs.

211. The statements above in ¶¶209-210 were materially false and misleading because Defendants failed to disclose that, as detailed above at ¶¶75-100, the Company's positive financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, as stated above in ¶¶38-55 & 73-74, Defendants failed to disclose that the Company's financial results were achieved in material part because Defendants did not spend the necessary funds on critical quality function.

2. 2Q08 10-Q

212. On January 8, 2008, Immucor filed its Form 10-Q with the SEC for the period ending November 30, 2007 ("2Q08 10-Q"). The 2Q08 10-Q was signed by Defendant De Chirico.

213. In the 2Q08 10-Q, Defendants represented that as part of the immunohematology industry, Immucor was regulated by the FDA. In addition, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

214. The 2Q08 Press Release, the 2Q98 Conference Call, the 2Q08 10-Q and the statements in ¶213 above were materially false and misleading because, as set forth in ¶¶38-55 & 60-61 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

   b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

   c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. 820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDR's to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses

which were essential for it to continue to function as a profitable and viable company.

215. The 2Q08 10-Q included the financial results identified above in ¶209 and also stated the following concerning its positive financial results and price increases of blood reagents:

> Revenue increased by 14% and 19% during the three months and six months ended November 30, 2007, respectively, compared to revenue earned in the corresponding periods of fiscal 2007. These improvements were largely attributable to the price increases in our traditional reagents (reagents not using our patented Capture technology) introduced in fiscal 2006 and 2007, and to a lesser extent due to exchange gains and sales volume increases in Capture products and instruments.
>
> …
>
> Of the $7.5 million total increase in revenues in the second quarter of fiscal 2008 compared to the corresponding quarter of fiscal 2007, approximately $6.6 million came from price increases in the United States.
>
> …
>
> Of the $20.1 million total increase in revenues in the six months ended November 30, 2007 compared to the corresponding period of fiscal 2007, approximately $15.3 million came from price increases in the United States.
>
> …
>
> The 15% and 18% growth in traditional reagent revenue in the three-month and six-month periods ended November 30, 2007, respectively, compared to the corresponding periods of fiscal 2007 occurred mainly as a result of price increases in the United States. Traditional reagent sales have historically been our primary source of revenue and still constitute roughly 70% of our revenues.

…

> Gross margins on traditional reagents for the three-month periods ended November 30, 2007 and November 30, 2006 remained at 75%. Gross margin on traditional reagents improved by 3% to 77% in the six-month period ended November 30, 2007 compared to the corresponding period of fiscal 2007 primarily due to price increases.

216. The 2Q08 10-Q made the following representations concerning the FTC's investigation of Immucor and possible violations of antitrust laws:

> On October 12, 2007, the Company received a letter from the Federal Trade Commission ("FTC") requesting that the Company voluntarily provide certain documents and information to the FTC concerning three acquisitions made by the Company in the period from 1996 through 1999, and concerning the Company's product pricing activities since then. The letter states the request is part of a non-public investigation by the FTC of whether the Company violated federal antitrust laws or engaged in unfair methods of competition through those acquisitions, and whether the Company or others engaged in unfair methods of competition by restricting price competition. The FTC letter states that neither the letter nor the existence of the investigation indicates that the FTC has concluded that the Company or anyone else has violated the law. The Company intends to cooperate with the FTC in this investigation, and is in the process of responding to the FTC's request. At this time the Company cannot reasonably assess the timing or outcome of the investigation or its effect, if any, on the Company's business.

217. The statements above in ¶¶215-216 were materially false and misleading because Defendants failed to disclose that the Company was operating in violation of U.S. antitrust laws and improving its revenues and financial results through collusive, anticompetitive pricing behaviors in violation of U.S. antitrust

laws as detailed above at ¶¶75-100. In addition, Defendants failed to disclose that the Company's positive gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function as detailed above in ¶¶38-55 & 73-74.

Q. January 2008 Inspection Identifies Recurring Violations from Prior Inspection

218. Between January 8 and 17, 2008, the FDA conducted another inspection of Immucor's Norcross facility and again, found a number of different violations of critical FDA regulations. In fact, at that inspection, the FDA found that several of the violations identified were recurring deficiencies from the March 2006 inspection. These recurring problems included "investigations into process deviation and non-conforming product were not always conducted or not always complete" in violation of 21 C.F.R. §820.100 (*i.e.*, root cause failures), inadequate policies and procedures concerning MDRs in violation of 21 C.F.R. §803.50(a)(2), "validation/qualification studies of processes, equipment and test methods were not always conducted or were incomplete" in violation of 21 C.F.R. §820.75(b) and "failure to establish and maintain procedures for changes to a specification, method, process, or procedure" in violation of 21 C.F.R. §820.70.

219. With respect to the Company's failure to properly conduct root cause investigations, the FDA found for example, that the Company had received a

number of complaints between November and December 2007 with respect one of the Company's products and that the Company had not investigated the root cause for the adverse trend.

220. Furthermore, during the January 2008 inspection Immucor was falsifying quality reports. CW1, who was closely involved with the January 2008 inspection, stated that FDA requested temperature records for review. However, these records were only partially complete. Accordingly, the Immucor employees involved in the inspection falsified historic temperature data and provided that to the FDA.

221. After being cited by the FDA nearly a year and a half earlier for a number of serious regulatory violations, the Company was still not in compliance and in fact, following the inspection, the FDA issued a Form 483 identifying fifteen different violations. Defendant De Chirico, along with CW1 and CW3 were present at the meeting to discuss the FDA's conclusions and the Company's various violations. Nevertheless, despite the FDA's findings of material noncompliance, the Company still did not disclose that its quality function was highly deficient and that as a result of the recurring quality control problems and Defendants' lack of commitment to quality that the Company's license was on the line.

R. 2008 Fiscal Third Quarter Statements

1. 3Q08 Press Release and Conference Call

222. On April 1, 2008, Immucor announced its fiscal third quarter results ("3Q08 Press Release"). In the press release, Defendant De Chirico discussed the Company "outstanding quarterly financial results" and the Company also stated:

> Revenue for the fiscal third quarter was $67.0 million, up 17% from $57.1 million in the same period last year. Of the $9.9 million total increase in revenues, approximately $4.6 million came from price increases in the United States.
>
> …
>
> Gross margin improved to 72.1% in the quarter compared to 70.7% in the prior year quarter. . . Reagent gross margin grew to 81.0% during the third quarter of fiscal 2008 compared to 77.6% in the same period last year. . . The gross margin on traditional reagents was 79.5% for the current quarter, compared with 75.5% in the prior year quarter.

223. On April 2, 2008, in a conference call with analysts ("3Q08 Conference Call"), in which Gallup and De Chirico participated, Defendants reiterated the Company's strong financial results. In addition, when asked about the Company's pricing strategy, Defendant De Chirico stated the "pricing model is very complex" and that pricing would depend on the "competitive landscape" as well as other factors. In addition, in discussing what Ortho, *i.e.* "J&J", was doing with prices as compared to Immucor, Defendant De Chirico stated:

> When our competitor at that time increased their price, we did a different strategy that was what we call the price differentiation strategy. Basically we, instead of doing a flat price increase, we increased the price over two year or three years, and we increased the price on different levels for different customers. And again, it's a complex picture, like I said before.

224. Defendants' statements above in ¶¶222-223 failed to disclose that as detailed above at ¶¶75-100 the Company's "outstanding quarterly financial results" were achieved through collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, as stated above in ¶¶38-62 & 73-74, Defendants failed to disclose that the Company's improved gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function.

2. 3Q08 10-Q

225. On April 2, 2008, Immucor filed its Form 10-Q with the SEC for the quarter ending February 29, 2008 ("3Q08 10-Q"). The 3Q08 was signed by Defendants De Chirico.

226. In the 3Q08 10-Q, Defendants represented that as part of the immunohematology industry, Immucor was regulated by the FDA. In addition, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

227. The 3Q08 Press Release, the 3Q08 Conference Call, the 3Q08 10-Q and the statements in ¶126 above were materially false and misleading because, as set forth in ¶¶38-62 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

   b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDR's to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations,

including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

228. The 3Q08 contained the financial results identified in the 3Q08 press release quoted above. In addition, the 3Q08 10-Q made the following additional statements:

> Revenue increased by 17% and 18% during the three months and nine months ended February 29, 2008, respectively, compared to revenue earned in the corresponding periods of fiscal 2007. These improvements were largely attributable to the price increases in our traditional reagents.
>
> …
>
> Of the $9.9 million total increase in revenues in the third quarter of fiscal 2008 compared to the corresponding quarter of fiscal 2007, approximately $4.6 million came from price increases in the United States.
>
> …
>
> Of the $30.0 million total increase in revenues in the nine months ended February 29, 2008 compared to the corresponding period of fiscal 2007, approximately $19.9 million came from price increases in the United States,
>
> …
>
> Gross margins on traditional reagents increased to 80% during the third quarter of fiscal 2008 from 75% during the corresponding quarter of fiscal 2007. Gross margin on traditional reagents improved by 3% to 78% in the nine-month period ended February 29, 2008 compared to the corresponding period of fiscal 2007. These gross margin increases were primarily due to price increases.

229. The statements above in ¶228 were materially false and misleading because Defendants failed to disclose that, as detailed above at ¶¶75-100, the Company's positive financial results were achieved through collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, as stated above in ¶¶38-62 & 73-74, Defendants failed to disclose that the Company's improved gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function.

S. FDA Issues a Warning Letter in May 2008

230. On May 2, 2008, the FDA sent a warning letter to Immucor, specifically addressed to Defendant De Chirico. In that warning letter, the FDA stated that as a result of the Company's "significant objectionable conditions" identified during the January 2008 inspection, the Company should take "prompt action to correct" the deviations identified by the FDA and that "[f]ailure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction."

231. The objectionable conditions identified by the FDA in the warning letter included but were not limited to failure to: (1) report changes to a specification, method, process or procedure to the FDA as required by 21 C.F.R.

§820.70; (2) adequately perform investigations, including addressing root causes, of nonconforming products and other quality problems in violation of 21 C.F.R. §820.100; and (3) submit Medical Device Reports to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2).

232. On May 13, 2008, Immucor disclosed that the FDA had issued a warning letter to the Company and falsely assured investors that Immucor was effectively addressing these problems:

> Our industry is highly regulated by the FDA, and we are subject to periodic inspection as a normal part of our business. ***We take our regulatory responsibilities very seriously and are working diligently to respond to the FDA as soon as possible.*** The FDA has not ordered the recall of any of our products, or placed any limitations on the manufacture or distribution of any of our products.

233. On June 5, 2008, in a 2009 guidance conference call with investors, in which Defendants Gallup and De Chirico participated, De Chirico stated the following in response to questions concerning the warning letter:

> …as many of you remember, we received this FDA warning letter at the beginning of May. We timely responded and proposed an action plan, timely responded. We had 15 working days to respond, we responded in less days than that. We sent this letter to FDA. We also have hired a consultant to assist us in helping us to get through this process. We proposed an action plan to FDA and at this point, that is what we have to do every day. ***We take our FDA responsibility very seriously and continue to work very hard to ensure full compliance***.

234. On June 6, 2008, the Company announced that the FDA had accepted Immucor's response to the warning letter. In that press release, Defendant De Chirico again stated "We take our regulatory responsibilities very seriously and worked diligently to respond to the FDA. We are pleased the FDA accepted our action plan, and was willing to move as quickly as it did. We have already begun implementing the plan."

235. Defendants' false assurances satisfied any market concerns. On June 9, 2008, a Natixis Bleichroeder analyst report stated that Immucor's announcement that the FDA had reviewed the Company's response to the warning letter and found that Immucor's proposed corrective actions were adequate was a "positive development" for Immucor as it "removes a potential risk to our target price".

236. The statements above in ¶¶232-234 were materially false and misleading because, as set forth in ¶¶38-64 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;
2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

T. 2008 Fiscal Fourth Quarter and Year End Statements

1. Fiscal Fourth Quarter and Year End 2008 Press Release and Conference Call

237. On July 23, 2008, Immucor announced its fiscal fourth quarter and year end results (the "4Q08 Press Release"). Defendant De Chirico praised the Company's positive financial results in stating: "All-time highs were achieved in revenues, gross margin, and net income for the year ended May 31, 2008. Our strategies to grow our business and the execution of our plan continue to generate outstanding results." The press release further represented:

> Revenue for the fiscal fourth quarter was a record $68.6 million, up 12% from $61.1 million in the same period last year. Of the $7.5 million total increase in revenues, approximately $3.7 million came from price increases in the United States.

238. On July 24, 2008, in a conference call with analysts ("4Q08 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendants reiterated the Company's "record" financial results. In addition, Gallup discussed the ongoing antitrust investigation, stated that the FTC had recently formalized its request into a "civil investigative demand or a CID" and that the Company was continuing to cooperate with the FTC.

239. The statements above in ¶¶237-238 were materially false and misleading because Defendants failed to disclose that as detailed above at ¶¶75-

100 the Company was engaged in an antitrust conspiracy and that its "all-time highs" and financial results were achieved through collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, as stated above in ¶¶38-64 & 73-74, Defendants failed to disclose that the Company's "all-time highs" in gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function.

2. 2008 10-K

240. On July 24, 2008, the Company filed its annual report on Form 10-K with the SEC for the period ending May 31, 2008 ("2008 10-K"). The 2008 10-K was signed by Defendants De Chirico and Eatz.

241. In the 2008 10-K, Defendants represented the following concerning the warning letter:

> The discovery of regulatory violations during such an inspection could subject us to significant adverse regulatory actions including warning letters, recalls or seizures of its products, a total or partial shutdown of production, the inability to obtain future marketing clearances or approvals, and withdrawals or suspensions of current products from the market. For example, in May 2008 we received an FDA warning letter related to certain ***perceived manufacturing and record-keeping problems***. In June 2008 the FDA completed its review of our response, notified us that no further response or information was needed and confirmed it would verify our corrective actions during a subsequent FDA inspection.

242. Defendants also stated that the Company was "highly regulated" and subject to "continuing compliance" with "regulations and standards that generally include . . . product testing [and] facilities compliance." In addition, Defendants represented:

> In the U.S., an FDA facility license is issued for an indefinite period of time, subject to the FDA's right to revoke the license. As part of its overview responsibility, the FDA makes plant and facility inspections on an unannounced basis. In 2006, we consolidated the Gamma Biologicals, Inc., Houston facility (U.S. Government Establishment License No. 435) under the Immucor, Inc. License No. 886, and subsequently discontinued operations at the Houston facility in December 2007. There are several FDA submissions associated with the transfer of manufacturing activities to Norcross and the FDA recently approved the transfer of manufacturing to our currently licensed facility in Norcross. Approval of our new manufacturing facility in Norcross is still pending.
>
> In addition, each product manufactured by us is subject to formal product submissions and review processes by the FDA . . . Significant changes to our products or facilities can require additional submission and review prior to implementation.

243. Moreover, Defendants falsely represented that Immucor's manufacturing and ongoing quality procedures were in compliance with federal regulations:

> In North America, we have hired and retained several employees who are highly experienced in FDA and other regulatory authority compliance, and we believe that our ***manufacturing and on-going quality control procedures conform to the required statutes, regulations and standards***.

244. In the 2008 10-K, Defendants also claimed that the Company "experienced a low staff turnover rate in fiscal 2008" and provided the following risk factor:

> ***We are highly dependent on our senior management team and other key employees, and the loss of one or more of these employees could adversely affect our operations.***
>
> Our success is dependent upon the efforts of our senior management and staff, including sales, technical and management personnel, many of whom have very specialized industry and technical expertise that is not easily replaced. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited. Our future success depends on our ability to continue to attract, retain and motivate qualified personnel. There is intense competition for medical technologists and in some markets there is a shortage of qualified personnel in our industry. If we are unable to continue to attract or retain highly qualified personnel, the development, growth and future success of our business could be adversely affected.

245. The 4Q08 Press Release, the 4Q08 Conference Call, the 2008 10-K and the statements above in ¶¶241-244 were materially false and misleading because, as set forth in ¶¶38-64 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;
2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

246. In addition, the statements in ¶244 above were materially false and misleading because as set forth in ¶¶43-44, there was a high-turnover rate in Immucor's quality department and significant reductions in headcount of quality positions.

247. Moreover, Defendants' statements concerning the warning letter were materially false and misleading because in stating that the warning letter merely pertained to "record-keeping problems", Defendants failed to disclose the seriousness of the deficiencies the FDA had identified. Defendants also falsely provided the impression to investors that the issues in the warning letter had been resolved.

248. The 2008 10-K contained the financial results quoted above at ¶237, stated that Immucor was "well positioned to compete favorably in [the blood banking industry]" and stated the following:

> Our revenue increased by 17% in fiscal year 2008 and by 22% in fiscal year 2007. Price increases in traditional reagents, volume increases in Capture products, increases in instrument revenue recognition and exchange gains mainly contributed to the revenue increases.
>
> …
>
> Of the $37.5 million total increase in revenues in the year ended May 31, 2008 compared to fiscal 2007, approximately $23.6 million came from price increases in the United States.
>
> …
>
> The 12% growth in traditional reagent revenue (i.e. products not using our patented Capture technology) in fiscal 2008 compared to fiscal 2007 occurred mainly as a result of price increases in the United States. Traditional reagent sales have historically been our primary source of revenue and still constitute roughly 69% of our revenue.
>
> …
>
> The 20% growth in traditional reagent revenue (i.e. products not using our patented Capture technology) in fiscal 2007 compared to fiscal 2006 occurred mainly as a result of price increases in the United States.

…

> Overall gross margin improved during fiscal 2007 to 71%, up from 66% in fiscal 2006, due to improvement in margins in all three main categories of our business. Gross margin on traditional reagents improved by 4% to 76% primarily due to price increases.

249. The statements above in ¶248 were materially false and misleading because, as detailed above at ¶¶75-100, Defendants failed to disclose that the Company's positive financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. Also, as stated above in ¶¶38-64 & 73-74, Defendants failed to disclose that the Company's improved gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function.

U. 2008 Annual Report

250. In or around July 24, 2008, Immucor provided its 2008 Annual Report ("2008 Annual Report") to its shareholders which included the 2008 10-K as well as a letter to the shareholders from Defendant De Chirico. In the letter to shareholders, De Chirico stated that delivering high quality was one of the Company's primary objectives. In addition, De Chirico stated:

> **Deliver High Quality.** Our industry is highly regulated by the FDA, and we are subject to periodic inspection as a normal part of our business. We are committed to continuously improving our quality system and during the year we invested in several initiatives that have already resulted in significant improvements. The commitment to quality at Immucor is company-wide and we are continually seeking opportunities for improvement.

251. The 2008 Annual Report and the statements above were materially false and misleading because, as set forth in ¶¶38-64 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the

Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

V. 2009 Fiscal First Quarter Statements

1. 1Q09 Press Release and Conference Call

252. On October 2, 2008, Immucor announced its fiscal first quarter results (the "1Q09 Press Release"). In that press release, defendant De Chirico stated that the Company was "very pleased with [its] record quarterly financial results." Furthermore, Immucor stated:

> Revenue for the fiscal first quarter was a record $73.2 million, up 15% from $63.6 million in the same period last year. Of the $9.6 million total increase in revenues, approximately $7.3 million came from price increases in the United States.
>
> …
>
> Gross margin was 73.0% in the quarter compared to 72.1% in the prior year quarter.

253. On October 2, 2008, in a conference call with analysts ("1Q09 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendants reiterated that they were extremely pleased with the Company's strong financial results. Defendant Gallup also provided an update concerning the FTC investigation and stated that "we are still not able to draw any conclusions about the outcome of this investigation." In addition, in response to a question from an analyst concerning competition in the industry, Defendant De Chirico stated:

> There is competition of course and we have several competitors in the US and many competitors around the world. And the comment we made at the beginning is that we are the only company in this industry who gives this kind of information. And of course we would like that our competitor becomes a little smarter and starts to work on their own business plan and not just looking at our business plan. I'm not going to give you a list of competitors that are out there, many companies who are in our industry who are working in our industry.

254. The statements above in ¶¶252-253 were materially false and misleading because as detailed above at ¶¶75-100 Defendants failed to disclose that the Company's "record" financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, as stated above in ¶¶38-64 & 73-74 Defendants failed to disclose that the Company's improved gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function.

2. 1Q09 10-Q

255. On October 2, 2008, Immucor filed a Form 10-Q with the SEC for the fiscal quarter ending August 31, 2008 ("1Q09 10-Q"). The 1Q09 10-Q was signed by Defendant De Chirico.

256. In the 1Q09 10-Q, Defendants represented that as part of the immunohematology industry, Immucor was regulated by the FDA. In addition, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

257. The 1Q09 Press Release, the 1Q09 Conference Call, the 1Q09 10-Q and the statements in ¶256 were materially false and misleading because, as set forth in ¶¶38-64 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important

to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or

procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

258. The 1Q09 10-Q contained the financial results identified above in ¶252 and stated the following concerning price increases:

> The 9% growth in traditional reagent revenue in the three-month period ended August 31, 2008, compared to the corresponding periods of fiscal 2008 occurred mainly as a result of price increases in the United States. Traditional reagent sales have historically been our primary source of revenue and still constitute roughly 70% of our revenues.

259. The 1Q09 10-Q made the following statement will respect to competition: "we expect increased competition, particularly in North America, to put downward pressure on prices, thereby reducing revenues and overall gross margin."

260. The 1Q09 10-Q provided an update concerning the FTC investigation into Immucor's antitrust violations and that on July 11, 2008, the FTC formalized its requests into a CID. Immucor further reiterated that the "issuance of a formal CID does not indicate any dissatisfaction with [Immucor's] cooperation [with the FTC's investigation]. As was previously the case, at this time the Company cannot reasonably assess the timing or outcome of the investigation or its effect, if any, on [its] business."

261. The statements above in ¶¶258-260 were materially false and misleading because as detailed above at ¶¶75-100 Defendants failed to disclose that the Company was engaged in an antitrust conspiracy and the Company's positive financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, Defendants failed to disclose that the Company's positive gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function, as detailed above in ¶¶38-64 & 73-74.

W. 2009 Fiscal Second Quarter Statements

1. 2Q09 Press Release and Conference Call

262. On January 7, 2009, Immucor announced its fiscal second quarter results (the "2Q09 Press Release"). The press release stated the following:

> Consolidated revenue increased approximately $11.1 million, or 18%, over the second quarter of fiscal 2008, driven by both price and instrument volume increases in the United States as well as increased sales outside the U.S. U.S. price increases accounted for approximately two-thirds of the total consolidated revenue increase. . .
>
> The year-over-year improvement in consolidated gross margins was driven by price increases in the U.S. . . .

263. On January 8, 2009 in a conference call with analysts ("2Q09 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendants reiterated Immucor's positive financial results.

264. The statements above in ¶¶262-263 were materially false and misleading because as detailed above at ¶¶75-100 Defendants failed to disclose that the Company's positive financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, Defendants failed to disclose that the Company's "year-over-year improvement in consolidated gross margins" was achieved in material part because Defendants did not spend the necessary funds on critical quality function, as detailed above in ¶¶38-64 & 73-74.

2. 2Q09 10-Q

265. On January 8, 2009, Immucor filed its Form 10-Q with the SEC for the period ended November 30, 2008 ("2Q09 10-Q"). The 2Q09 10-Q was signed by Defendant De Chirico.

266. In the 2Q09 10-Q, Defendants represented that as part of the immunohematology industry, Immucor was regulated by the FDA. In addition, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

267. The 2Q09 Press Release, the 2Q09 Conference Call, the 2Q09 10-Q and the statements in ¶266 above were materially false and misleading because, as set forth in ¶¶38-64 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important

to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or

procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a material risk of the FDA threatening to revoke or revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

268. The 2Q09 10-Q contained the financial results identified above and made the following additional statements:

> Of the $11.1 million total increase in revenues in the second quarter of fiscal 2009 compared with the prior year period, approximately $7.6 million came from price increases. . .
>
> Of the $20.6 million total increase in revenues in the six-month period ended November 30, 2008 compared to the corresponding period of fiscal 2008, approximately $15.0 million came from price increases…

> The 10% growth in traditional reagent revenue in the three-month and six-month periods ended November 30, 2008, compared to the corresponding periods of fiscal 2008 occurred mainly as a result of price increases in the United States.
>
> …
>
> For the three months ended November 30, 2008, our overall gross margin increased to 73.3% from 67.6% achieved in the corresponding quarter of fiscal 2008, primarily due to improvements of margins in traditional reagents and instruments.
>
> For the six months ended November 30, 2008, our overall gross margin increased to 73.2% from 69.9% achieved in the corresponding period of fiscal 2008, primarily due to improvements of margins in traditional reagents and instruments.
>
> For the three months ended November 30, 2008, gross margins on traditional reagents increased to 80.8% from 74.7% during the corresponding quarter of fiscal 2008. For the six months ended November 30, 2008, gross margins on traditional reagents increased to 79.7% from 77.2% during the corresponding period of fiscal 2008. Margin improvements in both current year periods were primarily due to increased pricing as well as more favorable manufacturing variances when compared to prior year periods.

269. The statements above in ¶268 were materially false and misleading because as detailed above at ¶¶75-100 Defendants failed to disclose that the Company's positive financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, Defendants failed to disclose that the Company's improvements in gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function, as detailed above in ¶¶38-64 & 73-74.

X. January 2009 Inspection Identifies Numerous Violations, including Recurring Violations

270. Between January 6 and January 16, 2009, the FDA inspected Immucor's Norcross facility for a third time during the Class Period and again found that the Company continued to be in violation of numerous federal regulations. For example, the FDA identified several recurring quality control deficiencies from the prior FDA inspections in March 2006 and January 2008, including: (1) "root cause/failure investigations and implementation of corrective actions are not sufficient and not conducted in a timely manner" in violation of 21 C.F.R. §820.100; (2) "validation/qualification studies of processes, equipment and test methods were not always conducted or were incomplete" in violation of 21 C.F.R. §820.75(b); (3) a number of violations of complaint handling procedures, which is a violation of 21 C.F.R. §820.198; and (4) failures concerning Immucor's "production and process controls", which is a violation of 21 C.F.R. §820.70.

271. The FDA also noted additional failures including that Immucor's products were shipped prior to completion of "out of specification [(OOS)] testing and/or OOS failure investigations." With respect to this problem, the FDA noted that this was also a repeat failure from the January 2008 inspection. In addition, the FDA stated that there hundreds of complaints in the Company's complaint database concerning product contamination.

272. With respect to the Company's root cause failures, the FDA noted that there was a "substantial increase in contamination events since the FDA inspection in January 2008" and that as a result of these failures "repeat failures are encountered". Thus, the FDA specifically attributed the Company's failures at this inspection to among other things, the recurring nature of the Company's failures to adequately address prior deficiencies.

273. At the close of the inspection, Defendant De Chirico was provided with the Form 483 identifying the eleven serious quality control deficiencies and as with prior inspection results, the FDA's conclusions were not made public at this time and Defendants failed to adequately disclose the true nature of the Company's quality control deficiencies.

Y. Statement by Defendant De Chirico in a Press Release

274. In a press release on January 19, 2009, Defendant De Chirico stated that Immucor had a "strong commitment to product quality and quality compliance".

275. The above statement was materially false and misleading because Defendants did not have a strong commitment to product quality or quality compliance. Instead, as detailed above in ¶¶38-68, Defendants continued to knowingly or were severely reckless in disregarding serious quality control

deficiencies even at this late stage, after being repeatedly warned by the FDA during three inspections, in March 2006, January 2008 and January 2009, as well by internal quality personnel. In fact, just prior to this announcement, between January 6-16, 2009, the FDA conducted an inspection of Immucor's Norcross facility and found numerous, serious and recurring objectionable conditions. For example, products were shipped out of the facility prior to testing or investigations being performed, there was a "substantial increase in contamination events" since the January 2008 inspection which the FDA attributed to the Company's improper handling of root cause investigations.

Z. 2009 Fiscal Third Quarter Statements

1. 3Q09 Press Release and Conference Call

276. On April 6, 2009, Immucor announced its fiscal third quarter results (the "3Q09 Press Release"). In the press release, Defendants represented:

> Gross margin was 72.6%, up from 70.7% in the prior year period.
>
> …
>
> Consolidated revenue was $75.3 million in the current year quarter, an increase of approximately $8.3 million, or 12%, over the third quarter of fiscal 2008. Reagent price increases and increased instrument revenue in the United States market as well as increased sales of reagents outside of the U.S. accounted for the majority of the revenue increase.

277. On April 7, 2009 in a conference call with investors ("3Q09 Conference Call"), in which Defendants Gallup and De Chirico participated, Defendants reiterated the Company's strong financial results.

278. The statements above in ¶¶276-277 were materially false and misleading because as detailed above at ¶¶75-100 Defendants failed to disclose that the Company's positive financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, Defendants failed to disclose that the Company's improvements in gross margins were achieved in material part because Defendants did not spend the necessary funds on critical quality function, as detailed above in ¶¶38-74.

279. In the conference call, Defendant Gallup also reiterated that Immucor was highly regulated by the FDA. With respect to the deficient January 2009 inspection, Defendant Gallup stated: "We recognize that our progress in improving our quality processes and systems needs to be faster than we could accomplish using our internal resources alone, ***a fact confirmed by a customary follow-up visit by the FDA."*** Defendant De Chirico further stated with respect to the January 2009 inspection:

> Well, like we said, in April 2008 we hired this consultant to help us to improve and offset our processes and quality systems. At the beginning of the third quarter we realized that what we were doing was not enough, and ***this was soon after confirmed by a routine visit***

> ***from FDA***, who confirmed that. And then we decided to expand to a much higher level the involvement of this consultant to be sure that we achieve our quality objectives.
>
> . . .
>
> ***Analyst***
> Earlier, you said that when you reviewed the quality issues, you thought you weren't doing enough. Can you just expand on that? How did you know you weren't doing enough?
>
> ***Dr. Nino De Chirico***
> Well, because we have a biweekly quality review meeting and we assess what we are doing and we assess -- and again, we had this consultant helping us to do the assessment. I was not pleased with the pace or the speed of the improvement. We were making improvements, but not at the speed I was -- we were expecting. Again, we are talking here about process and quality system related and not related to specific product performance.

280. Defendant Gallup also discussed a "quality process improvement project" implemented at the Company whose objective was "to deliver on [the Company's] world-class quality system." Furthermore, the Company stated that it had hired a consulting group to "provide guidance in improving [Immucor's] quality processes and systems." Also, again, Defendants stated: "We take our regulatory responsibility very seriously and implemented a remediation plan to address the FDA findings."

281. The 3Q09 Press Release, the 3Q09 Conference Call and the statements in ¶¶279-280 were materially false and misleading because, as set forth in ¶¶38-72 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

   b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

   c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDRs to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations, including the violations set forth above, Immucor faced a

material risk of the FDA revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

2. 3Q09 10-Q

282. On April 7, 2009, Immucor filed its Form 10-Q with the SEC for the period ending February 28, 2009 ("3Q 10-Q"). The 3Q09 10-Q was signed by Defendant De Chirico.

283. The 3Q09 10-Q made the following representations concerning a "quality process improvement project" that Immucor implemented during the fiscal quarter:

> During the fiscal third quarter, the Company began a quality process improvement project to enhance our operations and improve our quality initiatives. We spent approximately $0.5 million in the fiscal third quarter and expect to spend $1.5 million to $2.0 million in the fiscal fourth quarter related to the project.

284. In the 3Q09 10-Q, Defendants represented that as part of the immunohematology industry, Immucor was regulated by the FDA. In addition, Defendants stated that "regulatory obstacles" were one factor that could cause actual results to differ materially from those expressed in statements made by Immucor.

285. The 3Q09 10-Q and the statements in ¶¶283-284, were materially false and misleading because, as set forth in ¶¶38-72 above, Defendants failed to disclose that:

1. The quality function at Immucor was substandard and insufficient to ensure that the Company remain in compliance with FDA regulations;

2. The Company's Norcross operations were in material violation of FDA regulations and guidelines, including, but not limited to the following:

   a. De Chirico and Eatz focused on revenue to the detriment of quality, expressed the opinion that Immucor was too important to the market for the FDA to shutdown, viewed quality as nonessential to Immucor and failed to establish a commitment to quality nor implement a quality program that ensured compliance to FDA regulation in violation of 21 C.F.R. §820.20;

   b. Immucor failed to take corrective or preventive actions to correct for nonconforming products, including addressing root causes, in violation of 21 C.F.R. §820.100;

c. Immucor failed to perform validation/qualification analysis of process, equipment or methods as required by 21 C.F.R. §820.75(b);

d. Immucor failed to address complaints pursuant to 21 C.F.R. §820.198 including failures to investigate complaints, maintain records of investigations if performed and in certain cases failed to submit MDR's to the FDA within 30 days as required by 21 C.F.R. §803.50(a)(2); and

e. Immucor failed to monitor and control production controls to ensure that its processes conformed to specifications, including failing to report changes to a specification, method, process or procedure, adequately controlling for adverse environmental conditions as required by 21 C.F.R. §820.70; and

3. Defendants had failed to adequately address the material regulatory violations the FDA had identified during its recent inspection of the Company's Norcross facility, including those violations identified above; and

4. As a result of Defendants' lack of commitment to quality and disregard of Immucor's repeated violations of FDA regulations,

including the violations set forth above, Immucor faced a material risk of the FDA revoking Immucor's licenses which were essential for it to continue to function as a profitable and viable company.

286. Moreover, Defendants provided the impression that the January 2009 was a routine inspection in which only minor issues were identified however these deficiencies identified above were not minor in any way. For example, products were shipped out of the facility prior to testing or investigations being performed, there was a "substantial increase in contamination events" since the January 2008 inspection which the FDA attributed to the Company's improper handling of root cause investigations, and there were numerous customer complaints concerning problems with the Company's products not being properly handled. Due to the severity of the Company's deficient quality controls and the recurring nature of these numerous problems, the FDA proceeded to send a Notice of Intent to Revoke to Immucor for its various violations shortly after the filing of this 3Q09 10-Q.

287. The 3Q09 10-Q contained the financial results identified above in ¶276. In addition, the 3Q09 10-Q represented the following concerning the Company's positive financial results and price increases:

> Revenue increased by 12% and 15% during the three-month and nine-month periods ended February 28, 2009, respectively, compared with revenue earned in the corresponding periods of fiscal 2008. This increase was largely attributable to the price increases in our

> traditional reagents (reagents not using our patented Capture technology).
>
> …
>
> Of the $8.3 million total increase in revenues in the third quarter of fiscal 2009 compared with the prior year period, approximately $6.0 million came from price increases . . .
>
> Of the $28.9 million total increase in revenues in the nine-month period ended February 28, 2009 compared with the corresponding period of fiscal 2008, approximately $20.9 million came from price increases . . .
>
> Traditional reagent revenue in the three-month and nine-month periods ended February 28, 2009 increased 11% and 10%, respectively, compared with the corresponding periods of fiscal 2008 primarily as a result of price increases in the United States.
>
> …
>
> For the nine months ended February 28, 2009, our overall gross margin increased to 72.6% from 70.7% achieved in the corresponding period of fiscal 2008, primarily due to improvements of margins in traditional reagents and instruments.
>
> …
>
> For the nine months ended February 28, 2009, gross margins on traditional reagents increased to 79.2% from 78.0% during the corresponding period of fiscal 2008, primarily due to increased pricing.

288. The statements above in ¶287 were materially false and misleading because as detailed above at ¶75-100 Defendants failed to disclose that the Company's positive financial results were the result of collusive, anticompetitive pricing behaviors in violation of U.S. antitrust laws. In addition, Defendants failed to disclose that the Company's improved gross margins were achieved in material

part because Defendants did not spend the necessary funds on critical quality function, even after three failed inspections (in March 2006, January 2008 and January 2009) as well as the warning letter in May 2008, as detailed above in ¶¶38-74.

VII. LOSS CAUSATION

289. The Defendants' unlawful conduct alleged herein directly caused the losses incurred by Lead Plaintiff and the Class. Throughout the Class Period, the prices of Immucor securities were artificially inflated as a direct result of the Defendants' false and misleading statements and omissions alleged herein. The false and misleading statements set forth above were widely disseminated to the securities markets, investment analysts and to the investing public. The Company's true facts became known by investors and the market through a series of partial corrective disclosures, as set forth herein and summarized below. By making contemporaneous, additional misstatements in connection with these partial disclosures or by failing to reveal the falsity of all statements at one time, artificial inflation remained in Immucor securities throughout the Class Period.

290. As the true facts became known and/or the materialization of the risks that had been fraudulently concealed by the Defendants occurred, the price of Immucor securities declined precipitously as the artificial inflation was removed

from the market price of these securities, causing substantial damage to Lead Plaintiff and the members of the Class. Examples of specific dates of adverse disclosures and corresponding declines in the price of Immucor securities are set forth below.

A. Immucor's October 26, 2007 Disclosure

291. On October 26, 2007, Immucor disclosed that the FTC had formally requested documents and information related to a non-public investigation into whether three acquisitions made by Immucor from 1996 through 1999 and the Company's "product pricing since then" violated federal antitrust laws. However, Immucor pointed out that the FTC request stated that "neither the letter nor the existence of the investigation indicate[d] that the FTC [] concluded that Immucor or anyone else has violated the law."

292. As a result of this disclosure, at the close of the market on October 26, 2007, Immucor's common stock declined by $3.30 per share, a drop of 9.36%, to close at $31.95 per share on substantially greater than average trading volume.

B. Immucor's May 13, 2008 Disclosure

293. On May 13, 2008, during the trading day, Immucor disclosed that it was responding to an FDA warning letter.

294. Immucor's common stock price dropped following this news by 4.5%, or $1.26 per share, from $27.96 per share on May 12, 2008 to $26.70 per share at the close of the market on May 13, 2008, on unusually heavy trading volume.

295. In a conference call with analysts on June 5, 2008, Defendant De Chirico misleadingly stated that Immucor was working toward solving the deficiencies the FDA had identified and downplayed the significance of these problems in stating:

> [W]e received this FDA warning letter at the beginning of May. We timely responded and proposed an action plan, timely responded. We had 15 working days to respond, we responded in less days than that. We sent this letter to FDA. We also have hired a consultant to assist us in helping us to get through this process. We proposed an action plan to FDA and at this point, that is what we have to do every day. We take our FDA responsibility very seriously and continue to work very hard to ensure full compliance.

296. Analysts reacted positively to these false assurances. In fact, a Natixis Bleichroeder report dated June 9, 2008 states "On Friday, BLUD announced that the FDA reviewed the company's response to its previously issued warning letter. Accordingly, the FDA found BLUD's proposed corrective actions adequate and indicated that it will evaluate BLUD's progress at the next inspection. We view this is a positive development for BLUD, as it removes a potential risk to our target price."

C. Immucor's April 24, 2009 Disclosure

297. On April 24, 2009, prior to the market opening, Immucor announced that it had "received a subpoena from the United States Department of Justice, Antitrust Division, requesting documents for the period beginning September 1, 2000 through the present, pertaining to an investigation of possible violations of the federal criminal antitrust laws in the blood reagents industry."

298. Immucor's stock price plummeted nearly 27% on the news, from a closing price of $20.98 per share on April 23, 2009, to a closing price of $15.35 per share on April 24, 2009.

D. June 26, 2009 Disclosure

299. On June 26, 2009, prior to the market opening, Immucor announced that the FDA, in an administrative action based on a January 2009 inspection, issued a notice of intent to revoke the Company's biologics license with respect to two of the Company's major products: Reagent Red Blood Cells and Anti-E (Monoclonal) Blood Grouping Reagent.

300. In response to this news, the price of Immucor common stock dropped approximately 14.2% (or $2.29 per share) from $16.09 per share on June 25, 2009 to close at $13.80 per share on June 26, 2009.

301. Analysts reacted negatively to the news that Immucor's license for two of its important products was on the line. A June 26, 2009 Natixis Bleichroeder analyst report states:

> **The Letter That Might Break Investors' Backs; Downgrading to Hold**
>
> **Downgrading to Hold Because Even Though We Think Products Are Unlikely to Get Pulled, This News Just May Be the Straw That Breaks Investors' Backs.**
> . . . today's FDA letter has added an additional element of risk to the stock. . . until the FDA issue is resolved, we believe investors will be hesitant to put new money to work in this name. In combination with the previously announced Federal Trade Commission and Department of Justice investigations, the risks are difficult to quantify and likely to keep investors on the sidelines and the stock range bound.
>
> **…**
>
> While the FDA has not ordered a recall of the products, should the FDA proceed to revoke the company's license, BLUD would effectively be prohibited from selling the products in the U.S. As these products represent a significant portion of the company's total sales (estimated at around 25% of revenues, 30% of operating income), a negative action taken by the FDA could fundamentally alter the business.

302. In addition, in the earnings conference call on July 24, 2009, analysts were focused on both the FDA/quality control issues at Immucor as well as the governmental investigations into violations of the antitrust laws.

303. The price declines in Immucor common stock alleged herein directly and proximately resulted from the above discussed disclosures and were not caused by industry news, randomness, or by Immucor-related information unrelated to the

alleged fraud. Each of the above referenced disclosures partially corrected the false and misleading information previously available to the market by the Defendants' wrongful course of conduct.

VIII. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

304. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pleaded in this Complaint.

305. First, none of the statements complained of herein was a forward-looking statement. Rather they were historical statements or statements of purportedly current facts and conditions at the time the statements were made, including statements of reported financial results, as well as quality and manufacturing practices at Immucor.

306. To the extent any of the false or misleading statements alleged herein can be construed as forward-looking, the statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. As set forth above in detail, then-existing facts contradicted Defendants' statements regarding the Company's competitive pricing strategy, the Company's financial results and purported compliance with FDA regulations. Given the then-existing facts

contradicting Defendants' statements, the generalized risk disclosures made by the Company were insufficient to insulate Defendants from liability for their materially false and misleading statements.

307. To the extent that the statutory safe harbor may apply to any of these false statements alleged herein, Defendants are liable for those false forward-looking statements because at the time each of those statements were made the speaker actually knew the statement was false or the statement was authorized and/or approved by an executive officer of Immucor who actually knew that those statements were materially false when made.

IX. RELIANCE-FRAUD ON THE MARKET DOCTRINE

308. At all relevant times, the market for Immucor's securities was an efficient market for the following reasons, among others:

a. The Company's common stock was actively traded on the Nasdaq, a highly efficient market;

b. As a regulated issuer, the Company filed periodic public reports with the SEC; and

c. The Company regularly had conference calls with investors and issued press releases which were carried by national news wires.

Each of these releases was publicly available and entered the public marketplace.

309. As a result, the market for Immucor's securities promptly digested current information with respect to Immucor from all publicly available sources and reflected such information in the price of the Company's securities. Under these circumstances, all purchasers of the Company's publicly traded securities during the Class Period suffered similar injury through their purchase of the publicly traded securities of Immucor at artificially inflated prices, and a presumption of reliance applies.

X. CLAIMS FOR RELIEF

COUNT I

(For Violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) Against All Defendants)

310. Lead Plaintiff incorporates ¶¶1-309 by reference.

311. During the Class Period, the Defendants: (a) deceived the investing public, including Lead Plaintiff and other Class members, as alleged herein; (b) artificially inflated and maintained the market price of Immucor's securities; and (c) caused members of the Class to purchase Immucor's securities at artificially inflated prices.

312. The Defendants named in this count made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading, and/or substantially participated in the creation of the alleged misrepresentations, which operated as a fraud and deceit upon the purchasers of Immucor securities, in an effort to maintain artificially high market prices for Immucor securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5(b).

313. As a result of their making and/or their substantial participation in the creation of affirmative statements and reports to the investing public, the Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, as embodied in SEC Regulation S-K (17 C.F.R. § 229.10, et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations and performance, so that the market prices of Immucor's publicly traded securities would be based on truthful, complete and accurate information.

314. Defendants directly and indirectly, by the use of means and instrumentalities of interstate commerce and/or the mails, made, or substantially participated in the creation of, untrue statements of material facts and/or omitted to

state material facts necessary in order to make the statements made about the Company in light of the circumstances under which they were made, not misleading, as set forth herein.

315. The Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with severe reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were unavailable to them. The facts alleged herein set forth a strong inference that each of the Defendants acted with scienter.

316. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market prices of Immucor securities were artificially inflated throughout the Class Period. In ignorance of the fact that the market prices of Immucor's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by the Defendants, or upon the integrity of the market in which such shares trade, and the truth of any representations made to appropriate agencies and to the investing public, at the times at which any statements were made, and/or on the absence of material adverse information that was known or with severe recklessness disregarded by the Defendants but not disclosed in public statements

by these Defendants, Lead Plaintiff and the other members of the Class purchased Immucor securities at artificially high prices, and were damaged thereby.

317. At the time of said misrepresentations and omissions, Lead Plaintiff and the other members of the Class were ignorant of their falsity, and believed the false statements to be true. Had Lead Plaintiff and the other members of the Class and the marketplace known of the true nature of the operations of Immucor and the noncompliance with federal law, which were not disclosed by Defendants, Lead Plaintiff and the other members of the Class would not have purchased such stock or, if they had purchased such stock, they would not have done so at the artificially inflated prices which they paid.

318. Defendants acted with scienter in that they knew or were severely reckless in disregarding that the public documents and statements issued or disseminated in the name of Immucor were materially false and misleading, knew or were severely reckless in disregarding that such statements or documents would be issued or disseminated to the investing public, and knowingly or severely recklessly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents in violation of the federal securities laws.

319. As alleged herein, Defendants participated in the fraudulent scheme, by virtue of their receipt of information reflecting the true facts regarding Immucor, their control over, and/or receipt and/or modification of Immucor's allegedly materially misleading misstatements and/or their associations with Immucor which made them privy to confidential proprietary information concerning Immucor, participated in the fraudulent scheme alleged herein.

320. Defendants knew and/or were severely reckless in disregarding the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme alleged herein could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge or severe recklessness and complicity of the personnel at the highest level of the Company.

321. Defendants had the opportunity to perpetrate the fraudulent scheme and course of business described herein because they were the most senior officers and directors of Immucor, and they issued statements and press releases on behalf of Immucor and had the opportunity to commit the fraud alleged herein. As illustrated by the Defendants' respective positions with the Company, they had and used their influence and control to further the scheme alleged herein. The

Defendants had broad responsibilities that included communicating with the financial markets and providing the markets with financial results.

322. Defendants were privy to and directed the making of financial projections and results. By making the misleading statements contained herein, the defendants knew or were severely reckless in disregarding that they would artificially inflate the price of the Company's securities. Their respective actions resulted in damage to Lead Plaintiff and the Class.

323. By reason of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5(b), promulgated thereunder, and are liable to Lead Plaintiff and the other members of the Class for damages which they suffered in connection with their purchases of Immucor securities during the Class Period.

COUNT II

(For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants)

324. Lead Plaintiff incorporates ¶¶1-323 by reference.

325. Individual Defendants, by virtue of their respective offices and specific acts alleged above, including stock ownership, were, at the time of the wrongs alleged herein, controlling persons of Immucor within the meaning of Section 20(a) of the Exchange Act.

326. Defendants named in this count, had the power and influence and exercised the same to cause the Company to engage in the illegal conduct and practices complained of herein. The Individual Defendants each controlled Immucor through their respective executive and/or board positions.

327. As senior executive officers and/or directors of Immucor, the Individual Defendants had a duty to disseminate accurate and truthful information regarding Immucor's financial statements and to correct any previously issued statements that had become untrue so that the market price of Immucor securities would be based upon truthful and accurate information.

328. Defendants named in this count, by reason of their executive or directorial positions with Immucor, were controlling persons of Immucor, had the power to control the general affairs of Immucor, and had the power and influence, and exercised the same, to cause Immucor to engage in the conduct complained of herein. The Individual Defendants controlled the contents of Immucor's SEC filings, corporate reports and press releases. Each of the Defendants named in this count participated in writing or reviewing the Company's corporate reports, press releases, and SEC filings alleged to be misleading and thus had the ability and opportunity to prevent their issuance or cause them to be corrected and thereby culpably participated in the fraud alleged herein.

329. Because of their positions and access to material non-public information available to them, the Individual Defendants knew of or were severely reckless in disregarding that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. Thus, each of these Defendants is legally responsible for the falsification of Immucor's public reports, financial statements, press releases and other statements as alleged herein.

330. By reason of the conduct alleged herein, Defendants named in this count are liable for the aforesaid wrongful conduct, and are liable to Lead Plaintiff and to the other members of the Class for the damages which they suffered in connection with their purchases of Immucor securities during the Class Period.

XI. CLASS ACTION ALLEGATIONS

331. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Immucor securities during the Class Period, inclusive (the "Class"). Excluded from the Class are Defendants in this Action and their affiliates.

332. The members of the class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide

substantial benefits to the parties and the Court. As of March 31, 2010, there were 69,883,974 shares of common stock outstanding owned by many thousands of persons.

333. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the member of the Class which predominate over questions which may affect individual Class members include:

a. Whether the Exchange Act was violated by Defendants;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether the Defendants acted with the requisite state of mind;

e. Whether the price of Immucor securities was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damage.

334. Lead Plaintiff's claims are typical of those of the Class because Lead Plaintiff and the Class sustained damages from the Defendants' wrongful conduct.

335. Lead Plaintiff will adequately protect the interests of the Class and has retained counsel who is experienced in class action securities litigation. Lead Plaintiff has no interests which conflict with those of the Class.

336. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

XII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for judgment as follows:

A. Declaring the action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding Lead Plaintiff and the members of the Class damages, including interest;

C. Awarding Lead Plaintiff's counsel reasonable costs and attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Lead Plaintiff demands a trial by jury.

DATED: April 2, 2010

Respectfully Submitted,

/s/ *Frederic S. Fox*

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Liaison Counsel for Lead Plaintiff CAAT and the Proposed Class

Exhibit A

CERTIFICATION

I, Kevin Rorwick, Chief Financial Officer of the Colleges of Applied Arts and Technology Pension Plan ("CAAT"), hereby declare that:

1. I am authorized to make a certification on behalf of CAAT.

2. I have reviewed the Consolidated Amended Complaint filed in this action alleging violations of the securities laws and authorize its filing.

3. CAAT did not purchase the securities that are the subject of this action at the direction of the plaintiff's counsel or in order to participate in any private action arising under the federal securities laws.

4. CAAT is willing to serve as a representative party on behalf of a class, including providing testimony at deposition and trial if necessary. CAAT fully understands the duties and responsibilities of the Lead Plaintiff under the Private Securities Litigation Reform Act of 1995, specifically concerning its selection and retention of counsel and overseeing and directing the prosecution of the action on behalf of the class.

5. CAAT's transactions, during the class period, in the securities that are the subject of the Consolidated Amended Complaint are set forth in Schedule A attached hereto.

6. CAAT has not served or sought to serve as a class representative in any action brought under the federal securities laws filed during the 3-year period preceding the date on which this certification is signed.

7. CAAT will not accept any payment for serving as a representative party on behalf of a class beyond its pro-rata share of any recovery, except as ordered or approved by the court, including any reward to a representative plaintiff of reasonable costs and expense directly related to the representation of the class.

8. I declare under penalty of perjury that the foregoing is true and correct, executed on this 1ST day of April, 2010.

Kevin Rorwick
Chief Financial Officer, CAAT

SCHEDULE A

COLLEGES OF APPLIED ARTS AND TECHNOLOGY PENSION PLAN
Immucor Inc. Transactions during Class Period: 10/19/2005-6/25/2009

SECURITY NAME	CUSIP	TRANSACTION TYPE	TRADE DATE	SHARES	PRICE PER SHARE
IMMUCOR INC	452526106	PURCHASES	2/17/2009	4,000	$27.0856
IMMUCOR INC	452526106	PURCHASES	2/17/2009	1,300	$26.9840
IMMUCOR INC	452526106	PURCHASES	2/18/2009	27,200	$26.1906
IMMUCOR INC	452526106	PURCHASES	2/18/2009	2,600	$25.9650
IMMUCOR INC	452526106	PURCHASES	2/27/2009	2,000	$22.5520
IMMUCOR INC	452526106	PURCHASES	3/2/2009	16,600	$20.8369
IMMUCOR INC	452526106	PURCHASES	3/3/2009	18,700	$20.6491
IMMUCOR INC	452526106	PURCHASES	3/4/2009	3,700	$20.6815
IMMUCOR INC	452526106	PURCHASES	5/11/2009	400	$15.8905
IMMUCOR INC	452526106	PURCHASES	5/11/2009	11,000	$15.9000
IMMUCOR INC	452526106	PURCHASES	5/11/2009	2,100	$15.8932
IMMUCOR INC	452526106	PURCHASES	5/12/2009	5,400	$15.7597
IMMUCOR INC	452526106	PURCHASES	5/12/2009	800	$15.7682
IMMUCOR INC	452526106	PURCHASES	5/12/2009	400	$15.7700
IMMUCOR INC	452526106	PURCHASES	5/12/2009	6,500	$15.7755
IMMUCOR INC	452526106	PURCHASES	5/13/2009	3,000	$15.8000
IMMUCOR INC	452526106	PURCHASES	5/13/2009	9,400	$15.7359
IMMUCOR INC	452526106	PURCHASES	5/14/2009	4,900	$15.8470
IMMUCOR INC	452526106	PURCHASES	5/14/2009	4,300	$15.8959
IMMUCOR INC	452526106	PURCHASES	5/15/2009	3,200	$15.8724
IMMUCOR INC	452526106	PURCHASES	5/28/2009	6,900	$14.4597
IMMUCOR INC	452526106	PURCHASES	5/28/2009	4,200	$14.4444
IMMUCOR INC	452526106	PURCHASES	5/28/2009	2,100	$14.5000
IMMUCOR INC	452526106	PURCHASES	5/28/2009	5,900	$14.3895
IMMUCOR INC	452526106	PURCHASES	5/28/2009	23,300	$14.3815
IMMUCOR INC	452526106	SALES	6/22/2009	700	$15.8070
IMMUCOR INC	452526106	SALES	6/22/2009	10,600	$15.8158
IMMUCOR INC	452526106	SALES	6/22/2009	1,700	$15.8772
IMMUCOR INC	452526106	SALES	6/22/2009	8,300	$15.8293
IMMUCOR INC	452526106	SALES	6/23/2009	3,100	$15.5280
IMMUCOR INC	452526106	SALES	6/23/2009	200	$15.7827
IMMUCOR INC	452526106	SALES	6/23/2009	15,600	$15.5467
IMMUCOR INC	452526106	SALES	6/24/2009	700	$15.4850
IMMUCOR INC	452526106	SALES	6/24/2009	1,000	$15.4818
IMMUCOR INC	452526106	SALES	6/24/2009	5,200	$15.5012
IMMUCOR INC	452526106	SALES	6/25/2009	500	$15.6470
IMMUCOR INC	452526106	SALES	6/25/2009	18,000	$15.8236

Local Rule 7.1D Certification

Counsel for CAAT hereby certifies that the text of this pleading has been prepared with Times New Roman 14 point font, one of the fonts and point selections approved by the Court in Local Rule 5.1B.

DATED: April 2, 2010

Respectfully Submitted,

/s/ *Frederic S. Fox*

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Liaison Counsel for Lead Plaintiff CAAT and the Proposed Class

CERTIFICATE OF SERVICE

I, Frederic S. Fox, hereby certify that on April 2, 2010, I electronically filed the Consolidated Amended Class Action Complaint with the Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

DATED: April 2, 2010

/s/ *Frederic S. Fox*
Frederic S. Fox